CLEVELAND BIOLABS INC
Form 10-K
March 06, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K
(Mark One)
x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2017
or
¨Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number 001-32954
CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, NY 14203	(716) 849-6810
(Address of principal executive offices)	Telephone No.

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.005 per share	NASDAQ Capital Market

Securities Registered Pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer
Non-accelerated filer	¨	Smaller reporting company x
		Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2017, was $13,886,205. There were 11,279,834 shares of common stock outstanding as of March 5, 2018.

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DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's 2018 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2017.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements give our current expectations of forecasts of future events. All statements other than statements of current or historical fact contained in this annual report, including statements regarding our future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals or the impact of any laws or regulations applicable to us, and plans and objectives of management for future operations, are forward-looking statements. The words "anticipate," "believe," "continue," "should," "estimate," "expect," "intend," "may," "plan," "project," "will," and similar expressions, as they relate to us, are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual future results may differ materially from those discussed here for various reasons. Factors that could contribute to such differences include, but are not limited to:

- our need for additional financing to meet our business objectives;
- our history of operating losses;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our plans and expectations with respect to future clinical trials and commercial scale-up activities;
- our reliance on third-party manufacturers of our product candidates;
- future agreements with third parties in connection with the commercialization of any approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States, the European Union and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- government contracting processes and requirements;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the exercise of control over our company our by our majority stockholder;
- the geopolitical relationship between the United States and the Russian Federation, as well as general business, legal, financial and other conditions within the Russian Federation;
- our ability to obtain and maintain intellectual property protection for our product candidates; and
- the other factors discussed below in "Item 1A. "Risk Factors," in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other filings we make with the Securities and Exchange Commission.

Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

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PART I

Item 1. Business

When used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, the terms "Cleveland BioLabs," the "Company," "CBLI," "we," "us," and "our" refer to Cleveland BioLabs, Inc. and its consolidated subsidiaries, BioLab 612, LLC and Panacela Labs, Inc.

GENERAL OVERVIEW

Cleveland BioLabs is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Entolimod, a Toll-like receptor 5 ("TLR5") agonist, which we are developing as a medical radiation countermeasure ("MRC") for reducing the risk of death from Acute Radiation Syndrome ("ARS") is our most advanced product canidtate. Other indications, including immunotherapy for oncology, have been or may in the future be investigated as well.

Entolimod as a MRC is being developed under the United States Food & Drug Administration's ("FDA's" or "Agency's") Animal Efficacy Rule (the "Animal Rule") for the indication of reducing the risk of death following exposure to potentially lethal irradiation occurring as a result of a radiation disaster (see "– Government Regulation – Animal Rule"). We believe that entolimod is the most efficacious MRC currently in development. The following is a summary of the clinical development of entolimod as an MRC to date and its related regulatory status.

We have completed two Good Clinical Practices ("GCP") clinical studies designed to evaluate the safety, pharmacokinetics and pharmacodynamics of entolimod in a total of 150 healthy subjects. We have completed a Good Laboratory Practices ("GLP"), randomized, blinded, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on survival and biomarker induction in 179 non-human primates exposed to 7.2 Gy total body irradiation when entolimod or a placebo was administered at 25 hours after radiation exposure. We have also completed a GLP, randomized, open-label, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on biomarker induction in 160 non-irradiated non-human primates.

We met with the FDA in July 2014 to present our human dose-conversion and to discuss our intent to submit an application for pre-Emergency Use Authorization ("pre-EUA"), a form of authorization granted by the FDA under certain circumstances (see "– Government Regulation – Emergency Use Authorization"). The FDA confirmed that our existing efficacy and safety data and animal-to-human dose conversion were sufficient to proceed with a pre-EUA application and agreed to accept a pre-EUA application for review. The pre-EUA application was submitted in the second quarter of 2015. As part of the Company's response to pre-EUA review comments received from the FDA, we met with the Agency in the first quarter of 2016 to discuss various aspects of entolimod manufacturing. The Agency specified that the Company needs to establish comparability between the drug formulation used in previously conducted preclinical and clinical studies and the entolimod drug formulation proposed for commercialization under the pre-EUA. The FDA also indicated that further review of the pre-EUA dossier would not proceed until these comparability data have been evaluated by the Agency.

To establish the comparability of the older formulation and the new formulation, the FDA requested that we first perform a side-by-side analytical comparability study between the two entolimod drug formulations. Thereafter, the Agency requested that we conduct an in vivo study in non-human primates ("NHP") to establish bio-comparability. The side-by-side analytical comparability analysis of the two formulations of entolimod was completed in the fourth quarter of 2016. The report of these results was submitted to the FDA in the first quarter of 2017. The FDA has reviewed this data and provided its consent to commence the bio-comparability study in NHP in the second quarter of 2017. The bio-comparability study is currently ongoing. Following completion of the study and discussion of the submitted study results with the FDA, we expect the FDA to resume the review of our pre-EUA dossier.

If the FDA authorizes the application, then Federal agencies are free to procure entolimod for stockpiling so that the drug is available to distribute in the event of an emergency, i.e., prior to the drug being formally approved by FDA under a Biologics License Application ("BLA"). Such authorization is not equivalent to full licensure through approval of a BLA, but precedes full licensure, and, importantly, would position entolimod for potential sales in

advance of full licensure in the U.S. We further believe pre-EUA status will position us to explore sales opportunities with foreign governments.

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In addition, the Company has submitted a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA") for entolimod as a MRC in Europe. The MAA was validated by the EMA in the fourth quarter of 2017 and is currently under review by the Agency.

In September 2015, we announced two awards totaling approximately $15.8 million in funding from the United States Department of Defense ("DoD"), office of Congressionally Directed Medical Research Programs to support further development of entolimod as a MRC. These awards have funded, and will continue to fund, additional preclinical and clinical studies of entolimod, which are needed for a BLA. In October 2016, the DoD modified the original statement of work of one of these contracts (Joint Warfighter Medical Research Program ("JWMRP") contract award number W81XWH-15-C-0101) by eliminating certain tasks no longer deemed critical for the preparation of the BLA and established new tasks to address the formulation questions raised by the FDA during the review of the pre-EUA dossier, including an aim to conduct an in vivo NHP bio-comparability study along with other drug manufacturing related activities. In September 2017, the DoD further modified the contract by extending its term to 2019 on a no-cost basis.

In addition to development work on the MRC for reducing the risk of death from ARS indication, we have completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. The data for the U.S. study were presented at the 2015 annual meeting of the American Society of Clinical Oncology ("ASCO"). Seven (7) additional patients have been dosed with the entolimod drug formulation proposed for commercialization under the pre-EUA and MAA in an extension of this study performed in the Russian Federation ("Russia"). Based on current plans, we hope to include up to 17 additional patients under this extension study prior to its completion in 2019.

We have also completed dosing of 40 patients in a study of the safety and tolerability of entolimod when administered as a neo-adjuvant therapy before cancer surgery in treatment-naïve patients with primary colorectal cancer. This study was performed in Russia using the entolimod dug formulation proposed for commercialization under the pre-EUA and MAA. Because this study included older patients (up to 84 years) and those with other health conditions, the trial further extended our understanding of entolimod effects in broader population of study patients. The safety profile of the drug appeared generally similar to the profiles previously identified in healthy subjects and patients with cancer who participated in prior studies. Increases in plasma cytokines and alterations of blood cells were observed that appeared consistent with TLR5-mediated mobilization and trafficking of immunocytes to peripheral tissues, although changes in tumor immune cell infiltration appeared to be independent of treatment group in this exploratory study. This study was partially funded by the development contract with the Russian Federation Ministry of Industry and Trade ("MPT").

Because both oncology studies performed in Russia used the entolimod drug formulation proposed for commercialization under the pre-EUA and MAA, the safety data from these studies was included in our MAA submission to the EMA for use of entolimod as a MRC.

CBLB612 is a synthetic molecule that activates the Toll-like heterodimeric receptor 2/6 ("TLR2/TLR6") and stimulated white blood cell generation in preclinical studies. Recently we have completed dosing in a Phase 2, randomized, placebo-controlled clinical study of CBLB612 as myelosuppressive prophylaxis in patients with breast cancer receiving doxorubicin-cyclophosphamide chemotherapy. While the efficacy hypothesis of the study was not confirmed, the CBLB612 appeared to be generally well tolerated at the doses used in this clinical trial. We currently have no active clinical studies ongoing with CBLB612.

Mobilan is a recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, a secretory non-glycosylated version of entolimod we are also developing through our subsidiary, Panacela Labs, Inc. ("Panacela"). Two randomized, placebo-controlled, dose-ranging studies of Mobilan in men with prostate cancer are currently ongoing in the Russian Federation.

CORPORATE INFORMATION

We were incorporated in Delaware in June 2003 as a spin-off company from The Cleveland Clinic. We exclusively license our founding intellectual property from The Cleveland Clinic. In 2007, we relocated our operations to Buffalo, New York and became affiliated with Roswell Park Cancer Institute ("RPCI"), through technology licensing and research collaboration relationships. Our common stock is listed on the NASDAQ Capital Market under the symbol "CBLI."

Our principal executive offices are located at 73 High Street, Buffalo, New York 14203, and our telephone number at that address is (716) 849-6810.

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Since inception we have formed several subsidiaries to best capitalize on our unique ability to leverage financial and clinical development resources in Russia. In December 2009, we created Incuron LLC ("Incuron") with BioProcess Capital Ventures ("BCV") to develop Curaxin compounds (defined below). In September 2011, we created Panacela, a U.S. entity, with Joint Stock Company "Rusnano" ("Rusnano") to develop Mobilan and other product candidates (described below.) Simultaneous with the formation of Panacela, was the creation of a wholly-owned Russian subsidiary of Panacela named Panacela Labs, LLC. Finally, we have a wholly-owned Russian subsidiary, BioLab 612, LLC. Incuron was included in our consolidated financial results through November 25, 2014, and then accounted for as an equity investment through April 29, 2015, after which our remaining equity interest in Incuron was sold by June 30, 2015. Currently we no longer own equity in Incuron, but do maintain a right to royalty payments, as later described, and we conduct drug development activities on behalf of Incuron in the U.S.

CBLI and Panacela each have worldwide development and commercialization rights to product candidates in development, subject to certain financial obligations to our current licensors.

The CBLI logo and CBLI product names are proprietary trade names of CBLI, its subsidiaries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols "®" and "™", respectively. Third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

PRODUCT DEVELOPMENT PIPELINE

Our product development programs arise from both internally developed and in-licensed intellectual property from our innovation partners, The Cleveland Clinic and RPCI. In building the Company’s product development pipeline, we intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities and ensures that our success is not dependent on any single product or indication. Our currently ongoing product development programs and their respective development stages are illustrated below:

CBLI

PRODUCT Indication	DISCOVERY	PRECLINICAL	PIVOTAL ANIMAL STUDIES	HUMAN SAFETY / DOSE CONVERSION
ENTOLIMOD-Biodefense Acute Radiation Syndrome				

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
ENTOLIMOD-Oncology Advanced Solid Tumors					

Panacela

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
MOBILAN Targeted Therapy of Prostate Cancer					

Our product development efforts were initiated by discoveries related to apoptosis, a tightly regulated form of cell death that can occur in response to internal stresses or external events such as exposure to radiation or toxic chemicals. Apoptosis is a major determinant of the tissue damage that occurs in a variety of medical conditions involving ischemia, or temporary loss of blood flow, such as cerebral stroke, heart attack and acute renal failure. In addition, apoptotic loss of cells of the hematopoietic system and gastrointestinal tract is largely responsible for the acute lethality of high-dose radiation exposure. On the other hand, apoptosis is also an important protective mechanism that allows the body to eliminate defective cells such as those with cancer-forming potential.

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We have developed novel strategies to target the molecular mechanisms controlling apoptotic cell death for therapeutic benefit. These strategies take advantage of the fact that tumor and normal cells respond to apoptosis-inducing stresses differently due to tumor-specific defects in cellular signaling pathways such as inactivation of p53 (a pro-apoptosis regulator) and constitutive activation of Nuclear Factor kappa-B ("NF-kB"), (a pro-survival regulator).

Thus, we designed two oppositely-directed general therapeutic concepts:

(a) temporary and reversible suppression of apoptosis in normal cells to protect healthy tissues from stress-induced damage using compounds we categorize as Protectans, which include entolimod, Mobilan, and CBLB612; and,

(b) reactivation of apoptosis in tumor cells to eliminate cancer using compounds we categorize as Curaxins, which includes CBL0137, currently being developed by our former subsidiary, Incuron.

In recent years, our understanding of the mechanisms of actions underlying the activity of these compounds has grown substantially beyond the initial founding concepts around modulation of apoptosis.

Entolimod Biodefense Indication

Our most advanced Protectan product candidate is entolimod, an engineered derivative of the Salmonella flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. We are developing entolimod as a medical radiation countermeasure for reducing the risk of death from ARS, which we refer to as a Biodefense Indication.

The market for medical radiation countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack in the U.S. Terrorist activities worldwide have continued in the intervening years and the possibility of chemical, biological, radiation and nuclear attacks continues to represent a perceived threat for governments world-wide. In addition to the U.S. government, which maintains a national stockpile of products for emergency use (the "National Stockpile"), we believe the potential markets for the sale of radiation countermeasures include U.S. federal, state and local governments, including defense and public health agencies; foreign governments; non-governmental organizations; multinational corporations; transportation and security companies; healthcare providers; and, nuclear power facilities.

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the hematopoietic system and gastrointestinal tract, which leads to ARS, a potentially fatal condition. The threat of ARS is primarily limited to emergency/defense scenarios and is significant given the possibility of nuclear/radiological accidents, warfare or terrorist incidents. The scale of possible exposure (number of people affected) has been estimated by the U.S. government to be in the range of 500,000 based on a modeled 10-kiloton device detonation in New York City. We believe the significant limitations of the two currently approved treatments to deal with such an event make entolimod a compelling product candidate. It is not feasible or ethical to test the efficacy of entolimod as a radiation countermeasure in humans. Therefore, we are developing entolimod under the FDA’s Animal Rule guidance (see "– Government Regulation – Animal Rule"). The Animal Rule authorizes the FDA to rely on data from animal studies to provide evidence of a product’s effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the product. Under these requirements, and with the FDA’s prior agreement, medical countermeasures, like entolimod, may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies, evidence of safety derived from studies in humans and any additional supporting data.

Our pivotal efficacy study conducted in 179 non-human primates demonstrated with a high degree of statistical significance that injection of a single dose of entolimod given to rhesus macaques 25 hours after exposure to a 70% lethal dose of total body irradiation improved animal survival by nearly three-fold compared to the control group. Dose-dependence of entolimod’s efficacy was demonstrated with doses above the minimal efficacious dose establishing a plateau at approximately 75% survival at 60 days after irradiation, as compared to 27.5% survival in the placebo-treated group.

Our pivotal study conducted in 160 non-irradiated non-human primates established the dose-dependent effect of entolimod on biomarkers for animal-to-human dose conversion.

Our clinical studies of entolimod in 150 healthy human subjects demonstrated the safety profile of entolimod and established the dose-dependent effect of entolimod on efficacy biomarkers in humans. In these studies, and in the oncology studies in which 63 cancer patients have been administered to date, transient decrease in blood pressure and elevation of liver enzymes were observed along with transient mild to moderate flu-like syndrome. Such effects are the most common adverse events and they are linked to up-regulation of cytokines that are also biomarkers for efficacy.

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As discussed above, we are seeking pre-EUA authorization from the FDA for entolimod, for which we submitted an application in 2015 and have had subsequent discussions with the FDA. Also, as noted above, we have submitted a MAA to the EMA for entolimod as a MRC in Europe. The MAA was evaluated in the end of the fourth quarter of 2017 and is currently under review by the EMA.

The FDA has granted Fast Track status to entolimod (see "– Government Regulation – Fast Track Designation") and Orphan Drug status for prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster (see "– Government Regulation – Orphan Drug Designation"). In January 2016, the EMA granted entolimod Orphan Drug Designation for treatment of ARS (see "– Government Regulation – Orphan Drug Designation") and has validated the Pediatric Investigational Plan ("PIP") that is required prior to an MAA approval.

Entolimod Oncology Indication

In addition to developing entolimod as a MRC for reducing the risk of death from ARS, we have initiated an evaluation of entolimod's potential to treat cancer by activating the innate and adaptive immune response in patients. In preclinical studies, entolimod produced tissue-specific activation of innate immune responses via interaction with its receptor, TLR5, and the liver was identified as a primary mediator of entolimod activity. Entolimod has also been shown to have a direct cytotoxic effect on tumors expressing TLR5 in animal models. Evaluations of local administration of entolimod in organs expressing TLR5, such as the bladder, have also been performed in animal models.

We completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. in 2015 and an extension study in additional patients in Russia receiving the entolimod drug product formulation proposed for commercialization is ongoing. The data for the U.S. study were presented at the 2015 annual meeting of ASCO. Twenty-six patients with previously treated metastatic cancers, including colorectal, non-small cell lung, anal and urothelial bladder tumors were enrolled in the study. Stable disease for more than 6 weeks was observed in 8 patients with various cancer types; among these, 3 patients (with anal, colorectal and urothelial cancers) had maintenance of stable disease for more than 12 weeks. Patients exhibited $CD8^+$ T-cell activation with stable or decreased levels of myeloid-derived suppressive cells, accompanied by increased immunostimulatory cytokines (G-CSF, IL-6, and IL-8). The tolerability profile in patients with advanced cancer was similar to that observed in two previously conducted studies in 150 healthy subjects receiving entolimod. As expected with activation of innate immune pathways, common adverse events were flu-like symptoms and fever, with some patients having transient, spontaneously resolving tachycardia, hypotension and hyperglycemia. Overall, treatment with entolimod was well tolerated.

In addition, we have conducted a clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy before cancer surgery in treatment-naïve patients with primary colorectal cancer. Because the study included older patients (up to 84 years) and those with other health conditions, the trial further extended an understanding of entolimod effects in a broader population of study patients. The safety profile of the drug appeared generally similar to the profiles previously identified in healthy subjects and patients with cancer who participated in prior studies. Increases in plasma cytokines and alterations of blood cells were observed that appeared consistent with TLR5-mediated mobilization and trafficking of immunocytes to peripheral tissues, although changes in tumor immune cell infiltration appeared to be independent of treatment group in this exploratory study. This study was partially funded by the MPT development contract.

In February 2016, we announced the publication of studies elucidating immunotherapeutic mechanisms through which entolimod suppresses metastasis in Proceedings of the National Academy of Sciences of the United States of America ("PNAS"). The studies presented in the PNAS publication decipher the cascade of cell-signaling events that are triggered by entolimod activation of the TLR5 pathway in the liver. The data also define the functional roles of natural killer ("NK"), dendritic, and CD8+ T-cells in the drug’s activity as a suppressor of metastasis. The studies demonstrate that entolimod administration induces chemokines that attract NK cells to the liver via a CXCR3-dependent mechanism. CXCR3 is a chemokine receptor that is highly expressed on both NK and effector T cells and plays an important role in cell trafficking to tissues. Once in the liver, NK cells, which are components of the innate immune system, engage an adaptive antitumor immune response through dendritic cell activation. This NK-to-dendritic cell

interaction generates CD8+ T-cell-dependent antitumor memory that results in tumor rejection upon animal re-challenge with tumor. Importantly, localized antitumor effects in the liver combine with systemic responses that enable suppression of metastasis to the lung.

We have exclusive worldwide development and commercialization rights to entolimod.

CBLB612

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CBLB612 is a proprietary compound based upon a natural activator of another tissue-specific component of the innate immune system, the TLR2/TLR6 heterodimeric receptor. CBLB612 is a pharmacologically optimized synthetic molecule that structurally mimics naturally occurring lipopeptides of Mycoplasma (a genus of parasitic bacteria) and activates NF-kB pro-survival and immunoregulatory signaling pathways via specific binding to TLR2 on a subset of body tissues and cell types that express this receptor. Preclinical studies have shown that CBLB612 stimulates white blood cell regeneration.

In July 2015, we reported the results of a Phase 1, single-center, blind, placebo-controlled, single ascending dose study in Russia evaluating the safety and tolerability of CBLB612 in healthy volunteers and measuring response of various hematopoietic stem and progenitor cell types in order to gain a preliminary estimate of the drug's hematopoietic stem cell stimulatory efficacy. Analysis of data from the 56 healthy volunteers enrolled in the study indicates that single subcutaneous injections of CBLB612 in doses ranging from 0.5 to 4 micrograms were generally well-tolerated, with the 4 microgram dose identified as the maximum tolerated dose. Observed adverse events were typically mild or moderate in severity, transient, and related to the drug's mechanism of action. Single injections of CBLB612 induced dose-dependent increases in absolute neutrophil counts lasting approximately 20 hours. Administrations of CBLB612 also resulted in rapid, dose-dependent increases of plasma levels of the specified cytokines. Cytokine levels returned to baseline levels several hours after administration of the drug.

Recently we have completed dosing in a Phase 2, randomized, placebo-controlled clinical study of CBLB612 as myelosuppressive prophylaxis in patients with breast cancer receiving doxorubicin-cyclophosphamide chemotherapy. Objectives of the study included evaluation of the depth and duration of chemotherapy-induced neutropenia and thrombocytopenia, progenitor cell and reticulocyte mobilization, changes in plasma cytokines, and safety. While the efficacy hypothesis of the study was not confirmed, the CBLB612 appeared to be generally well tolerated at the doses used in this clinical trial.

These two clinical studies were supported by a 139 million ruble matching funds development contract that we received in July 2012 from MPT (see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations"). We currently have no active clinical studies ongoing with CBLB612.

We licensed CBLB612 to Zhejiang Hisun Pharmaceutical Co., Ltd. for the territories of China, Taiwan, Hong Kong, and Macau. We have rest-of-world development and commercialization rights to CBLB612.

Mobilan

Mobilan is the lead product candidate of Panacela. Mobilan is a recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, a secretory non-glycosylated version of entolimod. In preclinical studies, delivery of Mobilan to tumor cells results in constitutive autocrine TLR5 signaling and strong activation of the innate immune system with subsequent development of adaptive anti-tumor immune responses.

Panacela has completed enrollment of patients in a Phase 1 multicenter, randomized, placebo-controlled, single-blinded study in Russia evaluating single injections of ascending doses of Mobilan administered directly into the prostate of patients with prostate cancer. In addition, in July 2016, recruitment of prostate cancer patients was opened in another multicenter, randomized, double-blind study in Russia evaluating the safety, pharmacodynamics, and efficacy of different treatment regiments of Mobilan.

These studies were partially funded under a 149 million ruble matching funds development contract that Panacela received in October 2013 from MPT which concluded as of December 31, 2016.

Panacela holds exclusive worldwide development and commercialization rights to Mobilan.

As of December 31, 2017, we owned 67.57% of Panacela.

CBL0137

CBL0137 is a small molecule with a multi-targeted mechanism of action that may be broadly useful for the treatment of many different types of cancer and is being developed by Incuron. During 2015 we sold our remaining equity interest in Incuron but retain a 2% royalty on (a) product sales of CBL0137, (b) consideration received by Incuron from a licensee or sublicensee, and (c) consideration received in connection with the first change of control of Incuron. Incuron's royalty obligations continue until April 29, 2025.

CBL0137 may offer greater efficacy and substantially lower risk for the development of drug resistance than conventional chemotherapeutic agents. CBL0137 inhibits MYC protein, NF-kB, Heat Shock Factor Protein-1

("HSF-1"), and Hypoxia-inducible factor 1-alpha; these are transcription factors that are important for the viability of many types of tumors. The drug also activates tumor suppressor protein p53 by modulating intracellular localization and activity of chromatin remodeling complex Facilitates Chromatin Transcription ("FACT"). CBL0137 has been shown to be efficacious in animal models of colon, lung, breast, renal,

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pancreatic, head and neck and prostate cancers; melanoma; glioblastoma; and neuroblastoma. It has also been shown to be efficacious in animal models of hematological cancers, including lymphoma, leukemia and multiple myeloma. Incuron is currently enrolling patients with advanced, solid tumors into two Phase 1 studies, one in Russia evaluating the oral administration of CBL0137 and one in the U.S. evaluating the intravenous administration of CBL0137. These studies are designed to investigate the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of CBL0137. Incuron is conducting these parallel evaluations of oral and intravenous routes of administration and continuous low-dose versus interrupted high-dose schedules to reduce the company's developmental risk by fully characterizing the clinical pharmacology of CBL0137.

In addition, Incuron is recruiting patients into a Phase 1 dose escalation and cohort-expansion study of intravenous formulation of CBL0137 in previously treated patients with hematological cancers in the U.S.

Incuron holds worldwide development and commercialization rights to CBL0137.

STRATEGIC PARTNERSHIPS

Since our inception, strategic alliances and collaborations have been integral to our business. We have exclusively licensed rights in each of our technologies from The Cleveland Clinic and RPCI and maintain innovative partnerships with each. We have also leveraged the experience, contacts and knowledge of our founders to engage financial partners in Russia. Through these partnerships we have collaborated with world-class scientists to develop our novel technologies and accessed non-traditional funding sources, including U.S. federal and foreign government contracts and project-oriented funding. We have received project-oriented funding from Rusnano through the formation of Panacela.

Both Panacela, as well as our wholly owned subsidiary BioLab 612, maintain operations in Russia and benefit from programs supporting domestic pharmaceutical industry development in Russia.

The Cleveland Clinic

In July 2004, CBLI entered into an exclusive license agreement with The Cleveland Clinic ("The Cleveland Clinic License"), pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic's research base underlying our therapeutic platform. We amended The Cleveland Clinic License effective as of September 22, 2011, pursuant to which we were granted an exclusive license to The Cleveland Clinic's research base underlying certain product candidates in development by Panacela ("Panacela Products"), including Mobilan and several earlier-stage compounds that are not currently material to our business. In consideration for The Cleveland Clinic License, we agreed to issue The Cleveland Clinic common stock and make certain milestone, royalty, and sublicense royalty payments as described below.

The Cleveland Clinic License requires milestone payments, which may be credited against future royalties owed to The Cleveland Clinic, as described in the table below.

Milestone Description	For Products Limited to Biodefense Uses	For All Other Products (Maximum amount)*
For any IND filing for a product	$ 50,000	$ 50,000
For any product entering Phase II clinical trials or similar registration	100,000	250,000
For any product entering Phase III clinical trials	—	700,000
For any product license application, BLA or NDA Filing for	350,000	1,500,000

a product**		
Upon regulatory approval permitting any product to be sold to the commercial market	1,000,000	4,000,000

Maximum amounts listed for achievement of milestone in U.S. If milestones are reached in another country first, * milestone payments will be prorated for certain products under the license based on the market size for the product in such country as that market relates to the then current U.S. market.

** New Drug Application ("NDA")

We have also agreed to make milestone payments of up to approximately $6.5 million for each Panacela Product that achieves certain developmental and regulatory milestones, provided that if CBLI or an affiliate of CBLI and The Cleveland Clinic jointly own the Panacela Product, the milestone amounts will be reduced by 50%.

The Cleveland Clinic License requires royalty payments of (a) 2% of net sales of any product candidate under a licensed patent solely owned by The Cleveland Clinic; and (b) 1% of net sales of any product candidate under a licensed patent that is jointly

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owned by The Cleveland Clinic and CBLI or an affiliate of CBLI. Further, if CBLI receives upfront sublicense fees or sublicense royalty payments for sublicenses granted by CBLI to third parties for any licensed patents solely owned by The Cleveland Clinic, CBLI will pay The Cleveland Clinic (i) 35% of such fees if the sublicense is granted prior to filing an IND application, (ii) 20% of such fees if the sublicense is granted after an IND filing but prior to final approval of the Product License Application or NDA, or (iii) 10% of such fees if the sublicense is granted after final approval of the relevant Product License Application or NDA, provided that such sublicense fees shall not be less than 1% of net sales. The above sublicense fees and sublicense royalty payments are reduced by 50% if The Cleveland Clinic and CBLI or an affiliate of CBLI jointly own the licensed patent.

Through December 31, 2017, CBLI had paid The Cleveland Clinic $150,000 for milestone payments on products limited to biodefense uses, and $400,000 for all other products.

As each patent covered by The Cleveland Clinic License expires, the license agreement will terminate as to such patent. The Cleveland Clinic may terminate The Cleveland Clinic License upon a material breach by us, as specified in the agreement. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice. CBLI may terminate The Cleveland Clinic License in its entirety or any specific patent licensed under the agreement by giving at least 90 days written notice of such termination to The Cleveland Clinic. The agreement will, subject to certain exceptions, automatically terminate with respect to a licensed product if The Cleveland Clinic does not receive a royalty payment for more than 1-year after the payment of royalties has begun.

Roswell Park Cancer Institute

We have entered into a number of agreements with RPCI relating to the licensure and development of our product candidates including:

- Two exclusive license and option agreements effective December 2007 and September 2011;
- Various sponsored research agreements entered into between January 2007 to present; and
- Clinical trial agreements for the conduct of our Phase 1 entolimod oncology study and Incuron’s Phase 1 CBL0137 intravenous administration study.

In December 2007, CBLI entered into an agreement with RPCI pursuant to which CBLI has an option to exclusively license any technological improvements to our foundational technology developed by RPCI for the term of the agreement. We believe our option to license additional technology under the agreement potentially provides us with access to technology that may supplement our product pipeline in the future. In consideration for this option and exclusive license, we agreed to make certain milestone, royalty and sublicense royalty payments. Additionally, RPCI may terminate the license upon a material breach by us. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice. The license does not have a specified term; however, as each patent covered by this license agreement expires, the royalties to be paid on each product relating to the licensed patent shall cease.

In September 2011, Panacela entered into an agreement with RPCI (the "Panacela-RPCI License") to exclusively license from RPCI certain rights to the Panacela Products, including Mobilan and several earlier-stage compounds that are not currently material to our business, and to non-exclusively license from RPCI certain know-how relating to the aforementioned product candidates for the limited purposes of research and development and regulatory, export and other government filings. Additionally, under the Panacela-RPCI License, Panacela has a right to exclusively license from RPCI (i) any technological improvements to the Panacela Products developed by RPCI before September 2016, and (ii) any technology jointly developed by Panacela and RPCI. In consideration for the Panacela-RPCI License, Panacela agreed to issue RPCI common stock and to make certain milestone, royalty and sublicense royalty payments as described below.

The Panacela-RPCI License requires milestone payments for developmental and regulatory milestones reached in the U.S. of up to approximately $2.5 million for each Panacela Product that achieves certain developmental and regulatory milestones. Additionally, Panacela will owe additional payments of up to approximately $275,000 for each other country where a licensed Panacela Product achieves similar milestones.

The Panacela-RPCI License requires royalty payments on net sales based on percentages in the low single digits. In addition, if Panacela sublicenses any of the licensed Panacela Products, Panacela will owe sublicensing fees ranging

from 5% to 15% of any fees received from the sublicensee by Panacela or an affiliate depending upon whether or not an IND has been filed or final approval of the relevant NDA has been obtained for such licensed product.

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As each patent covered by the Panacela-RPCI License expires, the license agreement will terminate as to such patent. In addition, the license agreement will terminate with respect to the licensed know-how after 20 years. RPCI may terminate the license upon a material breach by us, as specified in the agreement. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice (or 30 days if notice relates to non-payment of amounts due to RPCI). Panacela may terminate the license agreement in whole or as to any specific patent licensed under the agreement by giving at least 60 days written notice of such termination to RPCI. The agreement will, subject to certain exceptions, automatically terminate with respect to a licensed Panacela Product if Panacela fails to market, promote and otherwise exploit the licensed technology so that RPCI does not receive a royalty payment during any 12-month period after the first commercial sale of such licensed product.

We have also entered into a number of sponsored research agreements with RPCI pursuant to which both parties have sponsored research to be conducted by the other party. Under our sponsored research agreement with RPCI, title to any inventions under the agreement is determined in a manner substantially similar to U.S. patent law, and we have the option to license from RPCI, on an exclusive basis, the right to develop any inventions of RPCI (whether solely or jointly developed) under the agreement for commercial purposes. In addition, the sponsored research agreement may be terminated by one party if the other party becomes subject to bankruptcy or insolvency, the other party is debarred by the U.S. government or the other party breaches a material provision of the agreement and fails to cure such breach within 20 days of receiving written notice.

Under the sponsored research agreements with RPCI, we own any invention that is described in our research plan, co-own any inventions not described in our research plan that are made by Dr. Andrei Gudkov, our Chief Scientific Officer, and RPCI owns any other inventions not described in our research plan. We further have a right to exclusively license from RPCI any invention developed under such sponsored research agreements that are owned by RPCI. Such sponsored research agreements with RPCI expire in 2018, although we expect to enter into similar future arrangements.

We entered into an asset transfer and clinical trial agreement with RPCI for the conduct, by RPCI, of our Phase 1 clinical trial to evaluate the safety and pharmacokinetic profile of entolimod in patients with advanced cancers, which has now been largely completed.

Rusnano

In 2011, we formed Panacela with Rusnano to carry out a complete cycle of development and commercialization in Russia for the treatment of oncological, infectious or other diseases. We invested $3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or exclusively licensed, as applicable, to Panacela worldwide development and commercialization rights to five preclinical product candidates in exchange for Panacela common shares. Rusnano invested $9.0 million in Panacela preferred shares and warrants. In 2013, Rusnano loaned Panacela $1.5 million through a convertible term loan (the "Panacela Loan"). In December of 2015, together with Rusnano, we recapitalized Panacela to fully retire the Panacela Loan and certain other trade payables. Rusnano maintained its ownership percentage in Panacela, while CBLI's ownership stake grew to 66.77%. As of December 31, 2017, we had an ownership stake of approximately 67.57%.

INTELLECTUAL PROPERTY

Our intellectual property consists of patents, trademarks, trade secrets, and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents for our technologies and products, maintain trade secrets, operate without infringing the rights of others, and prevent others from infringing our proprietary rights. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations, and methods of use. Some of our issued patents, and the patents that may be issued based on our patent applications, may be eligible for patent life extension under the Drug Price Competition and Patent Term Restoration Act of 1984 in the U.S., supplementary protection certificates in the European Union ("E.U.") or similar mechanisms in other countries or territories. The following are the patent positions relating to our product candidates as of December 31, 2017.

In the U.S., we have 22 issued patents or allowed patent applications relating to our clinical-stage programs expiring on various dates between 2024 and 2032 as well as numerous pending patent applications and foreign counterpart patent filings which relate to our proprietary technologies. These patents and patent applications include claims directed to compositions of matter and methods of use.

We have 17 issued or allowed U.S. patents covering entolimod, which expire between 2024 and 2032. These patents include composition of matter claims, as well as method of use claims relating to our biodefense and oncology indications, reducing effects of chemotherapy, and treatment of reperfusion injuries. In addition, we have pending U.S. patent applications related to compositions of matter, oncology methods of use, and others biodefense methods, which, if issued, will expire between 2025 and 2035.

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We have 4 issued or allowed U.S. patents covering CBLB612 and related agents, which expire between 2026 and 2027. These patents include composition of matter and methods of use claims.

We have one issued U.S. patent covering compositions of matter for various vectors, including Mobilan, which expires in 2032. We also have issued or allowed patents covering Mobilan and related agents, which expire in 2030 that cover a broad list of international territories including the E.U., Australia, Japan and Russia. These patents include composition of matter and methods of use claims.

In addition, as of December 31, 2017, we had more than a hundred additional patents and patent applications filed worldwide. Any patents that may issue from our pending patent applications would expire between 2024 and 2035, excluding patent term extensions. These patents and patent applications disclose compositions of matter and methods of use.

Our policy is to seek patent protection for the inventions that we consider important to the development of our business. We intend to continue to file patent applications to protect technology and compounds that are commercially important to our business, and to do so in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators, and contractors.

RESEARCH AND DEVELOPMENT

As of December 31, 2017, our research and development group, including Russian-based personnel, consisted of 10 individuals. Our research and development focuses on management of outsourced preclinical research, clinical trials, and manufacturing technologies. We invested $5.0 million and $6.5 million in research and development in the years ended December 31, 2017 and 2016, respectively.

SALES AND MARKETING

We currently do not have marketing, sales, or distribution capabilities. We do, however, currently have worldwide development and commercialization rights for products arising out of substantially all of our programs, as discussed above. In order to commercialize any of these drugs, if and when they are approved for sale, we will need to enter into partnerships for the commercialization of the approved product(s) or develop the necessary marketing, sales, and distribution capabilities.

COMPETITION

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes from both biotechnology and major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do, including, in some cases, considerably more experience in clinical testing, manufacturing, and marketing of pharmaceutical products. There are also academic institutions, governmental agencies, and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts. We expect to encounter significant competition for any products we develop. Our product candidates' competitive position among other biotechnology and biopharmaceutical companies will be based on, among other things, time to market, patent position, efficacy, safety, reliability, availability, patient convenience, ease of delivery, manufacturing cost, and price. In these cases, we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our business.

Specifically, the competition for entolimod and our other clinical-stage product candidates includes the following:

Entolimod Biodefense Indication

Product candidates for treatment of the ARS face significant competition for U.S. government funding for both development and procurement of medical countermeasures and must satisfy government procurement requirements for biodefense products. Currently the only FDA-approved drugs for the treatment of ARS are filgrastim (Neupogen™) and peg-filgrastim (Neulasta™). Filgrastim (granulocyte colony-stimulating factor ("GCS-F") and peg-filgrastim (PEGylated form of GCS-F) stimulate neutrophils and may reduce infection related to ARS. Unlike entolimod, these drugs do not improve platelet counts or lessen bleeding, and do not ameliorate gastrointestinal dysfunction due to ARS. In label-supporting survival studies, filgrastim and peg-filgrastim were administered repeatedly and treatment

was accompanied by laboratory monitoring and required intensive supportive care (including platelet transfusions). By contrast, entolimod survival studies included only a single injection, without any intensive medical support, which we believe makes it significantly more suitable for use in a mass-casualty situation.

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The U.S. government has purchased several colony stimulating factors to treat injuries to bone marrow in victims of radiological or nuclear accidents or acts of terrorism for the National Stockpile. In 2013 it obligated $157 million to Amgen USA, Inc., for 541,000 doses of Neupogen® and $37 million to Sanofi-Aventis U.S., LLC for 66,000 doses of Leukine® (granulocyte-macrophage colony-stimulating factor). In October 2016, the U.S. government purchased an additional $37.6 million worth of Leukine® and peg-filgrastim, Neulasta®, from Amgen USA, Inc., for another $37.7 million. The U.S government also announced that it continues to work with Sanofi-Aventis to support the studies needed to request FDA approval of Leukine®. These purchases were made using funding and authority provided through the Project BioShield Act of 2004. Under the Project BioShield Act, the U.S. government supports the advanced development and procurement of new medical countermeasures - drugs, vaccines, diagnostics, and medical supplies - to protect health against chemical, biological, radiological and nuclear threats.

In addition to the colony-stimulating factors, we are aware of a number of companies also developing radiation countermeasures to treat the effects of ARS including: Aeolus Pharmaceuticals, Araim Pharmaceuticals, Inc., Cellerant Therapeutics, Inc., Humanetics Corporation, Neumedicines, Inc., Pluristem Therapeutics, Inc, RxBio, Inc., and Soligenix, Inc. Although their approaches to treatment of ARS are different, we compete with these companies for U.S. government development funding and may ultimately compete with them for U.S. and foreign government purchase and stockpiling of radiation countermeasures.

Additionally, our ability to sell to the government also can be influenced by competition from the products, such as Neupogen®, Neulasta®, and Leukine®, which were previously purchased by the U.S. government for the National Stockpile.

Entolimod Immuno-Oncology Program and Mobilan

Immunotherapies are major drivers of commercial growth in cancer therapy and constitute the primary competition for a potential immunotherapeutic agent like entolimod or Mobilan. Examples of marketed drugs in these categories include: pembrolizumab (Keytruda®) (Merck) indicated for advanced melanoma, metastatic non-small cell lung cancer ("NSCLC"), recurrent or metastatic head and neck squamous cell carcinoma, refractory classical Hodgkin lymphoma, and urothelial carcinoma; nivolumab (Opdivo®) (Bristol-Myers Squibb Company) for advanced melanoma and metastatic squamous NSCLC, hepatocellular carcinoma, head and neck squamous cell carcinoma , renal cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, and high or mismatch repair deficient metastatic colorectal cancer; ipilimumab (Yervoy®) (Bristol-Myers Squibb) of unresectable or metastatic melanoma, and for non-muscle-invasive bladder cancer. These drugs may be appropriate combination partners for entolimod or Mobilan in the appropriate treatment settings. However, these drugs may also be competitors for the market share in the treatment of various tumor types.

CBLB612

Mitigation of chemotherapy-induced myelosuppression is a multi-billion-dollar commercial category within oncology. Filgrastim, (Neupogen®) (Amgen), and peg-filgrastim (Neulasta®) (Amgen), or various biosimilar versions of these drugs, are the current standards for treatment of this condition. Filgrastim and pegfilgrastim are well established as neutrophil support factors in patients with cancer undergoing myelosuppressive chemotherapy.

MANUFACTURING

Our product candidates are biologics and small molecules that can be readily synthesized by processes that we have developed. We do not own or operate manufacturing facilities for the production of our product candidates for preclinical, clinical or commercial quantities. We rely on third-party manufacturers, and in most cases only one third party, SynCo Bio Partners B.V., to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop.

GOVERNMENT REGULATION

Government authorities in the U.S. and in other countries regulate the research, development, testing, manufacture, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, quality control, labeling, and export and import of pharmaceutical products such as those that we are developing. We cannot provide assurance that

any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

U.S. Drug Development Process

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In the U.S., the FDA regulates drugs and drug testing under the Federal Food, Drug, and Cosmetic Act and in the case of biologics, also under the Public Health Service Act. Our product candidates must follow processes consistent with these legislations before they may be marketed in the U.S.:

- preclinical laboratory and animal tests performed in compliance with current GLPs;
- development of manufacturing processes which conform to current Good Manufacturing Practices ("GMPs");
- submission and acceptance of an Investigational New Drug ("IND") application which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in compliance with current Good Clinical Practices ("GCPs") to establish the safety and efficacy of the proposed drug for its intended use; or in the case of entolimod, for reducing the risk of death following exposure to potentially lethal radiation, we are required to perform pivotal animal studies in compliance with GLP and some aspects of GCP to establish efficacy; and
- submission to and review and approval by the FDA of a NDA or BLA prior to any commercial sale or shipment of a product; or in the case of entolimod a pre-EUA prior to sales to the National Stockpile.

Nonclinical testing. Nonclinical testing includes laboratory evaluation of a product candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including cGMP and GLP. Prior to the initiation of GLP animal studies, including our pivotal studies for development of entolimod under the Animal Rule, an Institutional Animal Care and Use Committee ("IACUC") at each testing site must review and approve each study protocol and any amendments thereto.

We must submit to the FDA the results of nonclinical studies, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first clinical trial of the drug as part of an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to the interstate shipment and administration of any new drug that is not the subject of an approved pre-EUA, NDA, or BLA. Nonclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

The IND process. The FDA requires a 30-day waiting period after the submission of an IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a "clinical hold" that may affect one or more specific studies or all studies conducted under the IND. In the case of a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials placed on hold can begin or continue. The IND application process may be extremely costly and could substantially delay development of our products. Moreover, positive results of preclinical animal tests do not necessarily indicate positive results in clinical trials.

Prior to the initiation of each clinical study, the corresponding clinical protocol must be submitted to the IND and to an independent Institutional Review Board ("IRB") at each medical site proposing to conduct the clinical trial. The IRB must review and approve each study protocol, and any amendments thereto, and study subjects must sign an informed consent. Protocols include, among other things, the objectives of the study, dosing procedures, subject selection, and exclusion criteria and the parameters to be used to monitor patient safety. Progress reports of work performed in support of IND studies must be submitted at least annually to the FDA. Reports of serious, unexpected, and related adverse events must be submitted to the FDA and the investigators in a timely manner.

Clinical trials. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The drug is introduced into healthy human subjects or patients with advanced disease (in the case of certain inherently toxic products for severe or life-threatening diseases such as cancer) and tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion;
-

Phase 2: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage; and

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- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy, and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

We cannot be certain that we will successfully complete any phase of clinical testing of our product candidates within any specific time period, if at all. Clinical testing must meet the requirements of IRB oversight, informed consent and GCP. The FDA, the sponsor, or the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the participants are being exposed to an unacceptable health risk.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These meetings typically occur prior to submission of an IND, at the end of Phases 1 and 2 and before NDA or BLA submission. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

The NDA or BLA process. If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA or BLA, as applicable. The NDA or BLA, as applicable, is a vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the U.S. The NDA or BLA, as applicable, must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the application, unless an exemption applies. Every newly marketed pharmaceutical must be the subject of an approved NDA or BLA.

Upon submission of an NDA or BLA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the prescription drug user fee law in effect at that time. Current timing commitments under the user fee law vary depending on whether an NDA or BLA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a product candidate subject to the completion of post-marketing studies, commonly referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a Risk Evaluation and Mitigation Strategies ("REMS").

Manufacturing and post-marketing requirements. If approved, a pharmaceutical may only be marketed in the dosage forms and for the indications approved in the NDA or BLA, as applicable. Special requirements also apply to any samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA’s GMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA, and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract

with third parties for manufacturing of our products, our ability to control third party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third party manufacturers to comply with GMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals. With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug’s approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Failure to comply with FDA requirements can have negative consequences, including adverse

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publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Animal Rule

In 2002, the FDA amended its requirements applicable to BLAs/NDAs to permit the approval of certain drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from clinical trial(s) in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, which are known as the "Animal Rule", authorize the FDA to rely on animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the agent. Under these requirements, and with the FDA's prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated under this rule must demonstrate effectiveness through pivotal animal studies, which are generally equivalent in design and robustness to Phase 3 clinical studies. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies must allow for selection of an effective dose in humans. Safety under this rule is established under preexisting requirements, including safety studies in both animals (toxicology) and humans. Products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution and requirements to provide information to patients.

We intend to utilize the Animal Rule in seeking marketing approval for entolimod as a medical radiation countermeasure because we cannot ethically expose humans to lethal doses of radiation. Other countries may not at this time have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no "Animal Rule" equivalent in countries other than the U.S., but some may have similar policy objectives in place for these product candidates. Given the nature of nuclear and radiological threats, we do not believe that the lack of established criteria for review and approval of these types of products in other countries will significantly inhibit us from pursuing sales of entolimod to foreign countries.

All data obtained from the preclinical studies and clinical trials of entolimod, in addition to detailed information on the manufacture and composition of the product, would be submitted in a BLA to the FDA for review and approval for the manufacture, marketing and commercial shipment of entolimod.

Emergency Use Authorization

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services ("DHHS"), may, under certain circumstances, issue an Emergency Use Authorization ("EUA"), that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;
- a determination by the Secretary of the DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- a determination by the Secretary of DHHS of a public health emergency that effects, or has the significant potential to effect, national security and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing a

disease attributable to the agents described above, that the product's potential benefits outweigh its potential risks and that there is no adequate approved alternative to the product.

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Although an EUA cannot be issued until after an emergency has been declared by the Secretary of DHHS, the FDA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited.

We submitted a pre-EUA in 2015 in order to inform and expedite the FDA's issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions. Additionally, there is no guarantee that the FDA will agree that entolimod meets the criteria for EUA, or, if they do agree, that such agreement by the FDA will lead to procurement by the U.S. or other governments or further development funding.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act (the "PREP Act"), provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products", including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of DHHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. Since 2007, the Secretary of DHHS has issued nine declarations under the PREP Act to protect countermeasures that are necessary to prepare the nation for potential pandemics or epidemics from liability. We believe, in the event of an emergency, were the FDA to issue an EUA for entolimod, it would receive protection under the terms of the PREP Act.

Fast Track Designation

Entolimod has been granted Fast Track designation by the FDA for reducing the risk of death following total body irradiation. The FDA's Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials and may submit portions of an NDA or BLA on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval, under which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued. Receipt of Fast Track designation does not guarantee that we will experience a faster development process, review or approval as compared to conventional FDA procedures or that we will qualify or be able to take advantage of the FDA's expedited review procedures.

Orphan Drug Designation

Entolimod has been granted Orphan Drug designation by the FDA for prevention of death following a potentially lethal dose of total body irradiation. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting fewer than 200,000 individuals in the U.S. or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the U.S. Orphan Drug designation must be requested before submitting an NDA or BLA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval

process.

If an Orphan Drug-designated product subsequently receives the first FDA approval for the disease for which it has such designation, the product will be entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances for seven years as compared to five years for a standard new drug approval. As referenced above, we have received Orphan Drug designation for entolimod. We intend to seek Orphan Drug designation for our other products as appropriate, but an Orphan Drug designation may not provide us with a material commercial advantage.

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Entolimod has also been granted Orphan Drug Designation in the E.U. As in the U.S., the E.U. may grant orphan drug status for specific indications if the request is made before an application for marketing authorization is made. The E.U. considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the E.U. A company whose application for orphan drug designation in the E.U. is approved is eligible to receive, among other benefits, regulatory assistance in preparing the marketing application, protocol assistance and reduced application fees. Orphan drugs in the E.U. also enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

Foreign Drug Development and Approval Regulation

In addition to regulations in the U.S., we are and will be subject to a variety of foreign regulations governing clinical trials and will be subject to a variety of foreign regulation governing commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country. Other countries, at this time, do not have an equivalent to the Animal Rule and, as a result, do not have established criteria for review and approval of these types of products outside their normal review process, but some countries may have similar policy objectives in place for these product candidates.

European Drug Development and Approval Regulations. The EMA is an E.U. agency responsible for the evaluation of medical products. Like the FDA, the EMA mandates preclinical testing, three phases of clinical trials, and a final approval procedure as part of the drug development process. In the U.S., however, clinical trials and market approval are conducted under the FDA supervision and no authorizations can be obtained at the state level. In the E.U., clinical trials are initiated on a member state level and market authorization may follow a centralized, decentralized, or a mutual recognition pathway. The centralized pathway allows a candidate drug to be reviewed by the EMA and recommended to the European Commission for final approval. This pathway is mandatory for therapeutics treating specific conditions, such as cancer, HIV/ AIDS, diabetes, and rare diseases. In the decentralized procedure, applications for market authorization by the European Commission can be simultaneously requested from each member state. In the mutual recognition procedure, a drug is first evaluated by a single member state and the assessment may be used to obtain market authorization in another member state. This process is common for the approval of generic pharmaceuticals.

Another difference in drug evaluation process is the metrics adopted for measuring drug efficacy. While both the FDA and the EMA recognize the importance of patient-reported outcomes, the EMA focuses on global assessments of patient-reported quality of life, whereas the FDA focuses on symptom-specific measures and requires early planning and cooperation with patient groups to determine the most important symptom concerns.

Market approval in the E.U. is further complicated by additional regulations adopted by some of the member states that ultimately determine which drug can actually be marketed in that specific state. For example, a drug approved by the EMA also needs approval from the Medicines and Healthcare Products Regulatory Agency in order to be marketed in the United Kingdom. In addition, the National Institute for Health and Care Excellence has to assess potential cost concerns to determine whether the same drug can be purchased by the National Health Service for patient use. Finally, the individual E.U. member states control sales and promotional activities of all pharmaceuticals. Consequently, the national regulatory authorities are responsible for regulating pharmaceutical advertising, which is instead less restrictive in the United States.

Despite the submission of identical clinical data supporting the same drug, the EMA and FDA can come to different evaluations and conclusions. Between 1995 and 2008, 20% of oncological pharmaceuticals were approved by either the FDA or the EMA, but not both, and 28% of approved drugs had significant variations in the label wording.

Russian Drug Development and Approval Regulations. Our Russian activities are regulated by the Ministry of Health of the Russian Federation ("Minzdrav"). This federal executive authority is responsible for developing state policies as well as normative and legal regulations in the healthcare and pharmaceutical industries, including policies and

regulations regarding the quality, efficacy and safety of pharmaceutical products.

In addition, the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation, known as Roszdravnadzor, is the executive authority subordinated to Minzdrav, which, among other things, (i) performs control and surveillance of certain activities, including preclinical and clinical trials, and monitors compliance with the state standards for medical products and pharmaceutical activities; (ii) issues licenses for the manufacture of drug products and pharmaceutical activities; (iii) grants allowance for clinical trials, use of new medical technologies and import and export of medical products, including import of products for use in clinical trials; and (iv) reviews and grants or denies registrations of medical products for sale in Russia.

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The principal statute that governs our activities in Russia is the Federal Law No. 61-FZ "On Medicine Circulation" of April 12, 2010 (as amended). This law regulates the research, development, testing, preclinical and clinical studies, state registration, quality control, manufacture, storage, transporting, export and import, licensing, advertisement, sale, transfer, utilization and destruction of medical products within Russia, among other things. All medical products must be registered in Russia and comply with stringent safety and quality controls and testing.

In addition, our activities are subject to a number of other Russian laws, regulations and orders relating to the drug development activities, taxation, corporate governance, employment and other areas. In particular, the incorporation, corporate governance, shareholders' rights, and contractual matters related to our Russian subsidiaries and joint ventures are governed by the Civil Code of the Russian Federation and the Federal Law No. 14-FZ "On Limited Liability Companies" of February 8, 1998 (as amended). In accordance with this legislation we must comply with certain shareholders’ and board of directors’ approval requirements, including those applicable to major and interested party transactions.

Also, pursuant to the Russian Labor Code, our Russian subsidiaries and joint ventures must enter into employment contracts with each employee, afford them at least 28 days paid vacation period, limit the working week to 40 hours per week and follow the code’s specific procedures in case of employment termination.

EMPLOYEES

As of February 12, 2018, CBLI and its consolidated subsidiaries had 19 employees, 13 of whom are located in the U.S. and 6 of whom are located outside of the U.S. Of these employees, 12 were employed on a full-time basis and 7 were employed on a part-time basis.

ENVIRONMENT

We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws and regulations have not had, and are not expected to have, a material effect on our capital expenditures, results of operations, or competitive position.

Item 1A. Risk Factors

Risks Relating to our Financial Position and Need for Additional Financing

We will require substantial additional financing in order to meet our business objectives.

Since our inception, most of our resources have been dedicated to preclinical and clinical research and development ("xR&D") of our product candidates. In particular, we are currently developing several product candidates, each of which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in the development of these product candidates. These expenditures will include costs associated with preclinical and clinical R&D, obtaining regulatory approvals, product manufacturing, corporate administration, business development, and marketing and selling for approved products. In addition, other unanticipated costs may arise. As of December 31, 2017, our cash, cash equivalents, and short-term investments amounted to $8.8 million. We believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan for at least 12 months beyond the filing date of this Annual Report on Form 10-K. Because the outcome and timing of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results, and costs of researching and developing our product candidates, and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for any of our product candidates that are approved for sale, including marketing, sales, and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;

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- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the success of the pre-EUA submission we made with the FDA, the success of the MAA we made with the EMA, and any future submissions in the U.S., E.U., and other countries that we may make; and
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any.

When our available cash and cash equivalents become insufficient to satisfy our liquidity requirements, or if and when we identify additional opportunities to do so, we will likely seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stockholders and could contain covenants that would restrict our operations. Furthermore, any funds raised through collaboration and licensing arrangements with third parties may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In any such event, our business prospects, financial condition and results of operations could be materially, adversely affected.

We may require additional capital beyond our currently forecasted amounts and additional funds may not be available when we need them, on terms that are acceptable to us, or at all. In particular, a decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, our patent licenses may be terminated, and we may be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations.

We have a history of operating losses. We expect to continue to incur losses and may not continue as a going concern.

We have incurred significant losses to date. We reported net losses of approximately $9.8 million and $2.6 million for the years ended December 31, 2017 and 2016, respectively. We expect significant losses to continue for the next few years as we spend substantial sums on the continued R&D of our proprietary product candidates, and there is no certainty that we will ever become profitable as a result of these expenditures. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our product candidates.

Our ability to become profitable depends primarily on the following factors:

- our ability to obtain adequate sources of continued financing;
- our ability to obtain approval for, and if approved, to successfully commercialize our product candidates;
- our ability to successfully enter into license, development or other partnership agreements with third-parties for the development and/or commercialization of one or more of our product candidates;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing, and distribution.

Even if we successfully develop and market our product candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2017, we had federal net operating loss carryforwards ("NOLs") of $139.7 million to offset future taxable income, which begin to expire if not utilized by 2023, and approximately $4.0 million of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $84.2 million, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $0.3 million, which begin to expire if not utilized by 2022.

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The purchase of 6,459,948 shares of common stock by Mr. Davidovich yielded a post-transaction ownership percentage of 60.2% for him. We believe it highly likely that this transaction will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code ("Section 382"). Consequently, the utilization of these NOL and tax credit carryforwards, as well as any additional NOL and tax credit carryforwards generated in 2015 through the issuance date of July 9, 2015, will be limited according to the provisions of Section 382, which could significantly limit the Company's ability to use these carryforwards to offset taxable income on an annual basis in future periods. As such, a significant portion of these carryforwards could expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carry forwards.

Risks Related to Product Development

We may not be able to successfully and timely develop our products.

Our product candidates range from ones currently in the research stage to ones currently in the clinical stage of development and all require further testing to determine their technical and commercial viability. Our success will depend on our ability to achieve scientific, clinical, and technological advances and to translate such advances into reliable, commercially competitive products in a timely manner. In addition, the success of our subsidiaries will depend on their ability to meet developmental milestones in a timely manner or to fulfill certain other development requirements under contractual agreements, which are prerequisites to their receipt of additional funding from their non-controlling interest holders or the government agency funding their R&D efforts. Products that we may develop are not likely to be commercially available for several years. The proposed development schedules for our products may be affected by a variety of factors, including, among others, technological difficulties, proprietary technology of others, the government approval process, the availability of funds, disagreements with the financial partners in our subsidiaries, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and the unproven technology involved, we may not be able to successfully complete the development or marketing of any products.

We may fail to develop and commercialize some or all of our products successfully or in a timely manner because:

- preclinical or clinical study results may show the product to be less effective than desired (e.g., a study may fail to meet its primary objectives) or to have harmful or problematic side effects;
- we fail to receive the necessary regulatory approvals or there may be a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or pre-EUA, MAA, NDA, or BLA preparation, discussions with the FDA, EMA, and other regulatory agencies, and their request for additional preclinical or clinical data or unexpected safety or manufacturing issues;
- our contract laboratories fail to follow good laboratory practices or sufficient quantities of the drug are not available for clinical studies or commercialization;
- we fail to receive funding necessary for the development of one or more of our products;
- they fail to conform to a changing standard of care for the diseases they seek to treat;
- they are less effective or more expensive than current or alternative treatment methods;
- patients withdraw or die during a clinical trial for a variety of reasons, including adverse events associated with the advanced stage of their disease and medical problems that may or may not be related to our products or product candidates;
- the clinical or animal trial design, although approved, is inadequate to demonstrate safety and/or efficacy;
- the third-party clinical investigators or contract organizations do not perform our clinical or animal studies on our anticipated schedule or consistent with the study protocol or do not perform data collection and analysis in a timely or accurate manner;
-

the economic feasibility of the product is not attainable due to high manufacturing costs, pricing or reimbursement issues, or other factors;

- one or more of our financial partners in our subsidiaries and us do not agree on the development strategy of our products; or

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- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized.

Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering entolimod for its biodefense indication to government agencies may require us to develop new sales, marketing or distribution capabilities beyond those already existing in the Company and we may not be successful in selling entolimod for its biodefense indication in the U.S. or in foreign countries despite our efforts. Selling oncology drugs will require a more significant infrastructure. We plan to sell oncology drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with a third party capable of providing these services and we can make no guarantee that we will be able to enter into a strategic collaboration in the future. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third party collaborations with our manufacturers. Manufacturers producing our product candidates must follow GMP regulations enforced by the FDA and foreign equivalents.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory, or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. In addition, to the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or pivotal animal studies do not demonstrate efficacy.

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must conduct extensive preclinical and clinical studies to demonstrate that our product candidates are safe and clinical or pivotal animal trials to demonstrate that our product candidates are efficacious. And for entolimod's biodefense indication we must demonstrate a logical dosing correlation between animals and humans. These R&D activities are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. In addition, we will likely outsource all or part of individual R&D activities and may not successfully or promptly finalize agreements for the conduct of these activities. Consequently, delays in completion of contracted activities may result.

Engagement of contract research organizations ("CROs"), study investigators, and other third parties for clinical or animal testing or data management services, for example, transfers substantial responsibilities to these parties. As such we are dependent on these parties to timely execute their contracted work in a quality manner that complies with relevant standards and regulations such as GLPs. Failure of these parties to deliver timely and quality services could result in delays in, or termination of, contracted R&D activities. For example, if any of our clinical trial sites fail to comply with GCPs or our pivotal animal studies fail to comply with GLP regulations we may be unable to use the data generated. Consequently, if contracted CROs or other third parties do not properly execute their duties or fail to meet expected deadlines, our research activities may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our pivotal nonclinical and clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our trial sites are not in compliance with applicable regulatory requirements for conducting such trials, we or they may receive warning letters or other correspondence detailing deficiencies and we

will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be the subject of an enforcement action, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or we may be criminally prosecuted.

In addition, a failure of one or more of our clinical trials or animal studies can occur at any stage of testing and such failure could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our

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operations. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us to commence a clinical trial, conduct a clinical trial at a prospective trial site or continue a clinical trial following amendment of a clinical trial protocol or an IACUC may not authorize us to commence an animal study at a prospective study site;
- we may decide, or regulators may require us, to conduct additional preclinical or clinical studies, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we may have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;
- regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;
- the cost of our clinical trials or animal studies could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study;
- the effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics; and
- our collaborators that conduct our clinical or pivotal animal studies could go out of business and not be available for FDA inspection when we submit our product for approval.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

Panacela has a significant non-controlling interest holder and, as such, may not be operated solely for our benefit.

As of December 31, 2017, we owned 67.57% of the equity interests in Panacela. Rusnano, a fund regulated by the Russian government, is a significant shareholder along with other minority shareholders. As such, we share ownership and management of Panacela with other parties who may not have the same goals, strategies, priorities or resources as we do.

Both we and Rusnano have certain rights, including the right to designate board members and the need for either supermajority votes or consent of all members of Panacela's board of directors in order to take certain actions. Additionally, the right to transfer ownership is restricted by rights of first refusal, tag along and drag along rights. Consequently, if a co-owner sells their equity interest to a new party, the new party may adversely affect the operation of Panacela. These restrictions lead to organizational formalities that may be time-consuming. In addition, the benefits from a successful product development effort are shared among the co-owners.

If parties on whom we rely to manufacture our product candidates do not manufacture them in satisfactory quality, in a timely manner, in sufficient quantities, or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not own or operate manufacturing facilities. Consequently, we rely on third parties as sole suppliers of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce supplies for preclinical, clinical, and pivotal animal studies and for commercial quantities of any products or product candidates that we market or may supply to our collaborators. We also rely on

third parties as sole providers of certain testing of our products. Our dependence on third parties for the manufacture and testing of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

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To date, our product candidates have only been manufactured in quantities sufficient for preclinical studies and initial clinical trials. We rely on a single contract organization, SynCo Bio Partners B.V., for production of each of our product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates in a timely and competitive manner. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities of the product candidate from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies and commensurate financial investments by the contract manufacturers. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage of supply, which could limit our sales and could initiate regulatory intervention to minimize public health risk.

Other risks associated with our reliance on contract manufacturers include the following:

- contract manufacturers may encounter difficulties in achieving volume production, quality control, and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates;
- if, for any circumstance, we are required to change manufacturers, we could be faced with significant monetary and lost opportunity costs with switching manufacturers. Furthermore, such change may take a significant amount of time. The FDA and foreign regulatory agencies must approve these manufacturers in advance. This requires prior approval of regulatory submissions as well as successful completion of pre-approval inspections to ensure compliance with FDA and foreign regulations and standards;
- contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with GMPs and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with GMPs and other FDA requirements or other regulatory requirements outside the U.S. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business;
- contract manufacturers might not be able or refuse to fulfill our commercial or clinical trial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market or clinical trial demands. For example, our current agreement with SynCo Bio Partners B.V. ("Synco") does not impose any obligation on Synco to reserve a minimum annual capacity for the production of entolimod, which could impair our ability to obtain product from them in a timely fashion;
- our product costs may increase if our manufacturers pass their increasing costs of manufacture on to us;
- if our contract manufacturers do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to obtain or maintain regulatory approvals for our products and product candidates and will not be able to successfully commercialize our products and product candidates. In such event, we may not be able to locate any necessary acceptable replacement manufacturers or enter into favorable agreements with such replacement manufacturers in a timely manner, if at all; and
- contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during the conduct of clinical trials or after marketing approval also require regulatory submissions and the demonstration to the FDA or other regulatory authorities that the product manufactured under the new conditions complies with GMPs requirements. These requirements especially apply to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about

changes in the manufacturing process must be submitted to

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the regulatory authorities and may require prior approval before implementation with the potential of substantial delay or the inability to implement the requested changes.

Risks Relating to Regulatory Approval

We may not be able to obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable.

The testing, marketing and manufacturing of any product for use in the U.S. and the E.U. will require approval from the FDA and the EMA, respectively. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Obtaining approval for products requires manufacturing the product and testing in animals and human subjects of substances whose effects on humans are not fully understood or documented. The manufacturing processes for our product candidates are not yet fully developed and identifying a reproducible process may prove difficult. Additionally, preclinical studies, animal efficacy studies, or clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive.

In addition, we expect to rely on the FDA Animal Rule to obtain approval for entolimod's biodefense indication in the U.S. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. Additionally, we submitted an application with the FDA for pre-EUA in 2015, so that entolimod may be used in an emergency situation. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for pre-EUA or BLA approval and require additional preclinical, clinical, or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. If we are not successful in completing the development, licensure, and commercialization of entolimod for its biodefense indication, or if we are significantly delayed in doing so, our business will be materially harmed.

Delays in obtaining FDA, EMA, or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product's potential commercial success and/or on our business, prospects, financial condition and results of operations.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to market our product candidates, including specifically the product candidates being developed by our Russian subsidiaries, in the U.S., Europe, Russia, and other countries and regulatory jurisdictions. In order to market our product candidates in the U.S., Europe, Russia, and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements to file for and obtain marketing approval for drugs in countries outside of the U.S., Europe, and Japan and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the U.S., Europe, and Japan. Also, the time required to obtain approval in markets outside of the U.S. may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the U.S. or the EMA in the E.U., does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not have established criteria for review and approval for this type of product outside their normal review process. Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for entolimod's biodefense indication outside the U.S. based on our animal efficacy and human safety data.

The Fast Track designation for entolimod may not actually lead to a faster development or regulatory review or approval process.

We have obtained a "Fast Track" designation from the FDA for entolimod’s biodefense indication. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA’s expedited

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review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

The pre-EUA submission we made to the FDA in 2015 may not be successful and, even if such submission is successful, it may not accelerate BLA approval of entolimod or result in any purchase by the U.S. government for this product.

In July 2014, we met with the FDA regarding human dose-conversion of entolimod and based on the results of that meeting, we submitted a pre-EUA dossier in the second quarter of 2015 in order to inform and expedite the FDA's issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions and, therefore, the timing of any approval of a pre-EUA submission is uncertain.

The FDA may decide not to accept the data or may decide that our data are insufficient for pre-EUA. The FDA may require additional Chemistry, Manufacturing, and Controls ("CMC"), preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. For example, in 2016, the FDA asked the Company to establish the comparability of an older formulation of entolimod that had been used for preclinical and clinical studies and a newer to-be-marked formulation. The FDA requested that we perform a side-by-side analytical comparability study and then an in vivo study in NHP to establish bio-comparability between the two entolimod drug formulations. The FDA indicated that further review of the pre-EUA dossier would not proceed until these bio-comparability data have been evaluated by the Agency. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that the FDA will not request any additional information related to our preclinical, clinical or manufacturing programs. Additionally, an authorization of our pre-EUA submission will not guarantee, and may not accelerate, BLA approval of entolimod as a radiation countermeasure.

Further, even if our pre-EUA submission is authorized, there is no guarantee that such authorization will lead to procurement by the U.S. or other governments or any additional development funding as it is possible that the U.S. or other government may not be interested in our product or our proposed terms of sale for any number of reasons including, but not limited to, lack of available funding, potential lack of government co-sponsorship of our pre-EUA, perceptions about the safety and effectiveness of entolimod, the storage requirements for entolimod or one of our competitors receiving pre-EUA authorization for their product. If we are not successful in partnering entolimod or completing the development, licensure and commercialization of entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

The MAA we made to the EMA in 2017 may not be successful and, even if approved, it may not result in any purchase by any governments in the E.U. for this product.

In 2017, we submitted a MAA to the EMA for use of entolimod as a medical radiation countermeasure in the European Union. The associated pediatric investigational plan passed its compliance check and our application was validated by the EMA. The MAA is now undergoing agency review and there can be no assurance that approval will be granted in a timely manner or at all. The EMA may decide not to accept the data. The EMA may require additional CMC, preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Further, even if our MAA is approved, there is no guarantee that such approval will lead to procurement by any governments in the E.U. or any additional development funding as it is possible that E.U. governments may not be interested in our product or our proposed terms of sale for any number of reasons including, but not limited to, lack of available funding, potential lack of government co-sponsorship of our MAA, perceptions about the safety and effectiveness of entolimod, the storage requirements for entolimod or one of our competitors also having its MAA approved for its product. If we are not successful in partnering entolimod or completing the development, licensure, and commercialization of entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

Even if our drug candidates obtain regulatory approval, we will be subject to ongoing government regulation.

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by international health authorities, including record-keeping requirements, submitting periodic reports, reporting of any adverse experiences with the product and complying with Risk Evaluation and Mitigation Strategies and drug

sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the authorities. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting non-approved or "off-label" indications or products. Failure to comply with these requirements could result in significant enforcement action by the international health authorities, including warning letters, orders to pull the promotional materials and substantial fines.

After the approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or regulatory agency-initiated action that could delay or prevent further

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marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA and other international health authorities are likely to require post-market clinical testing of products approved under the Animal Rule or similar regulations at the time of a declared emergency and may require post-market clinical testing of other products. They may also require surveillance to monitor the product's safety or efficacy to evaluate long-term effects. It is also possible that rare but serious adverse events not seen in our drug candidates may be identified after marketing approval. This could result in withdrawal of our product from the market.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

- perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;
- published studies demonstrating the safety and effectiveness of our drugs;
- adequate reimbursement for our products from payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

Risks Related to our Dependence on U.S. and Foreign Government Contracts and Grants

If we are unable to procure additional government funding, we may not be able to fund future R&D and implement technological improvements, which would materially harm our financial conditions and operating results.

In September 2015, we announced the grant of two awards from DoD, totaling approximately $15.8 million for advanced development of entolimod as a medical radiation countermeasure. In October 2016, we further announced that DoD modified the original statement of work for the JWMRP contract by eliminating certain tasks no longer deemed critical for the preparation of the BLA and established new tasks to address the formulation questions raised by the FDA during the review of the pre-EUA dossier such that the aggregate amount payable to CBLI was unaffected. In September 2017, the DoD further modified the contract by extending its term to 2019 on a no-cost basis. These awards will be earned as the contracted development work is performed over a three to five year period. For the years ended December 31, 2017 and 2016, we received 69.0%, and 35.4% of our revenues from the U.S. government; and, 0.0%, and 46.9% of our revenues from the Russian government, respectively.

These revenues have funded some of our operating costs and expenses and the two above-referenced DoD awards are expected to similarly fund some of our operating costs and expenses in the future. However, we will continue to incur substantial additional costs to fund our operations for which we may apply for other sources of government funding. If we do submit proposals for new grants or contracts, the review of such proposals and ultimate funding of an award may take significant time. Contract and grant awards are subject to a significant amount of uncertainty, including, but not limited to, successful negotiation and availability of funds. In addition, in our experience, contracts from Russian government entities require matching funds and posting of performance guarantees. Therefore, we expect that our acceptance of new contracts or grants from Russian government entities will also be subject to our ability to provide matching funds and to post performance guarantees.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our current grants or contracts are terminated, our ability to fund future operations would be diminished, which would negatively impact our ability to compete in our industry and could materially and adversely affect our business, financial condition and operating results.

Our future business may be harmed as a result of the foreign and U.S. government contracting process as it involves risks not present in the commercial marketplace.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts, both U.S. and foreign, which may be awarded through competitive bidding. For example, as described above, we recently received funding from DoD to support further development of entolimod. Additionally, in Russia we may seek additional

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funding from the Skolkovo Foundation or MPT. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and
- the risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

The U.S. government may choose to award future contracts for the supply of medical radiation countermeasures to our competitors instead of to us. If we are unable to win particular contracts, or if the government chooses not to fully exercise all options under contracts awarded to us, we may not be able to operate in the market for products that are provided under those contracts for a number of years. If we are unable to consistently win new contract awards, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

Additionally, government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts.

The market for U.S. and other government funding is highly competitive.

We periodically submit applications for funding of various research studies of our product candidates to the U.S. and other governments. There is no guarantee that any proposals that we plan to submit will be funded even if we receive positive reviews of such proposals as funding by the government is highly competitive and limited to the availability of funds. Failure to receive funding from U.S. and other government sources for the development of our product candidates could impair our ability to fund the development programs for our product candidates and thus could result in delays in development, or even stopping of development, of certain indications for our product candidates.

Notably, our biodefense product candidate, entolimod, faces significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if entolimod does not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in the biodefense industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

U.S. government agencies have special contracting requirements, which create additional risks.

We have historically entered into contracts with various U.S. government agencies. Due to these contracts with government agencies, we are subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit by the government at its sole discretion even after the end of the period of performance under the contract, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

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- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing contracts;
- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

Pursuant to our government contracts, we are generally permitted to retain title to any patentable invention or discovery made while performing the contract. However, the U.S. government is generally entitled to receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, our government contracts generally provide that the U.S. government retains unlimited rights in the technical data produced under such government contract.

Our business could be adversely affected by a negative audit by the U.S. government.

As a U.S. government contractor, we may become subject to periodic audits and reviews by U.S. government agencies such as the Defense Contract Audit Agency ("DCAA"). These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed and, such costs already reimbursed must be refunded.

Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, which have already been paid to us, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs, and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits, and other legal actions and liabilities to which purely private sector companies are not.

Risks Relating to our Intellectual Property

We rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights and we may be liable for infringing upon the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have entered into five separate exclusive license agreements to license from third parties our product candidates that are not owned by us and some product candidates are covered by up to three separate license agreements. Pursuant to these license agreements we maintain patents and patent applications covering our product candidates. We do not know whether any of these patent applications that are still in the approval process will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. Furthermore, parties making

claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others

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that infringe upon our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial and the litigation would divert our management's efforts and our resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we fail to comply with our obligations under our license agreement with third parties, we could lose our ability to develop our product candidates.

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained exclusive licenses for our product candidates from The Cleveland Clinic and RPCI with regard to the use of patent applications as described above and certain processes, products and information of others, these licenses could be terminated or expire during critical periods and we may not be able to obtain licenses for other rights that may be important to us, or, if obtained, such licenses may not be obtained on commercially reasonable terms. Furthermore, some of our product candidates require the use of technology licensed from multiple third parties, each of which is necessary for the development of such product candidates. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Additionally, the patents underlying any licenses may not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

Our current exclusive licenses impose various development, royalty, diligence, record keeping, insurance, solvency and other obligations on us. If we breach any of these obligations and do not cure such breaches within the relevant cure period, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

In addition, while we cannot currently determine the dollar amount of the royalty and other payments we will be required to make in the future under the license agreements, if any, the amounts may be significant. The dollar amount of our future payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

If we are not able to protect and control our unpatented trade secrets, know-how and other technology, we may suffer competitive harm.

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

Risks Relating to our Industry and Other External Factors

The biopharmaceutical market in which we compete is highly competitive.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. In addition, there are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing

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pharmaceutical and biotechnology products. Many of these companies have substantially greater financial, technical, research and development resources, and human resources than us. Competitors may develop products or other technologies that are more effective than those that are being developed by us or may obtain FDA or other governmental approvals for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

Our success depends, in large part, on our ability to identify, hire, integrate, retain, and motivate qualified executive officers and other key employees throughout all areas of our business. We greatly depend on the efforts of our executive officers to manage our operations. In addition, we utilize highly skilled personnel in operating and supporting our business, as we have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more members of our management, key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. Furthermore, we may be unable to attract and retain additional qualified executive officers and key employees as needed in the future. We currently do not maintain directors and officers liability insurance, which may make it more difficult for us to retain and attract talented and skilled directors and officers to serve our Company.

Additionally, we depend on our scientific, manufacturing, regulatory clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. Furthermore, to the extent that we are unable to engage certain collaborators or advisors for certain periods of time due to lack of relevant work or lack of available funds, there is a risk that such collaborators or advisors will not be available to provide services in the future at such time when there is available work and/or funds. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific, manufacturing, business development, regulatory, clinical collaborators, advisors, and opinion leaders in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. We face significant competition for this type of personnel and for employees from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

We may be subject to damages resulting from claims that we, our employees or our consultants have wrongfully used or disclosed alleged trade secrets of their former employers.

We engage as employees and consultants individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may become subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if the product candidates are sold commercially. An individual may bring a product liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;

- diversion of our management's time and attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues;

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- the inability to commercialize product candidates; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance and intend to expand such coverage from coverage for clinical trials to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage that will be adequate to satisfy any liability that may arise.

From time to time, we may also become subject to litigation, such as stockholder derivative claims or securities fraud claims, which could involve our directors and officers as defendants. We currently do not have director and officer insurance to cover such risk exposure for our directors and officers. Our certificate of incorporation and bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. We would be obligated to cover all such expenses for all directors and officers, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity.

Our former laboratories used, and our subtenants use, certain chemical and biological agents and compounds that may be deemed hazardous and we are subject to various safety and environmental laws and regulations. Our compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.

Until late 2013, we operated laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment and we currently sublease these laboratories for operation by other companies, which currently use hazardous materials. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal and we currently require that our laboratory sub-lessors do the same. We contracted with a third party to properly dispose of these materials and wastes and our laboratory sub-lessors now manage such contracts. We were and continue to be subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs if we unknowingly failed to comply with environmental laws and regulations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Political or social factors may delay or impair our ability to market our products.

Entolimod is being developed to treat ARS, which is a disease that may be caused by terrorist acts. The political and social responses to terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

We announced in September 2015 that we received two awards from the DoD for the further development of entolimod. We hope to receive additional funding in the future from U.S. or foreign government agencies for the development of entolimod and our products. Changes in government budgets and agendas, however, have previously

resulted in termination of our contract negotiations and may, in the future, result in future funding being decreased and de-prioritized. In addition, government contracts contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue development of entolimod or continue our other operations. Similarly, if our pre-EUA

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submission for entolimod is authorized by the FDA, but the U.S. government does not place sufficient orders for this product, our future business may be harmed.

Failure to comply with the U.S. Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.

We are required to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some that may compete with us, are not subject to these prohibitions. Furthermore, foreign jurisdictions in which we operate may have laws that are similar to the FCPA to which we are or may become subject. This may place us at a significant competitive disadvantage. Corruption, extortion, bribery, pay-offs, theft, and other fraudulent practices may occur from time to time in the foreign markets where we conduct business. Although we inform our personnel that such practices are illegal, we can make no assurance that our employees or other agents will not engage in illegal conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and similar foreign anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, such anti-bribery laws present particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees may be considered foreign officials.

Risks Related to Conducting Business in Russia

Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results.

BioLab 612 and Panacela Labs, LLC, which is the wholly-owned subsidiary of Panacela, conduct business, including clinical trials, in Russia through Russian legal entities. Also, Rusnano is a Russian joint-stock company created as a private equity and venture capital vehicle by the government of Russia. BioLab 612 owns the Russian intellectual property rights for entolimod’s medical applications and CBLB612. Panacela Labs, LLC owns the worldwide rights to Mobilan. Rusnano has certain shareholder rights which could block our ability to execute strategic transactions such as an asset sale or licensing arrangement. All clinical development activity conducted by these Russian entities was funded by grants from MPT. As such, any political, economic, or governmental instability in Russia could impact future funding, if any, by MPT, our access to trial data and our access to intellectual property for out-licensing purposes.

In addition to geopolitical events, other factors, including the steady fall in oil prices, the global strengthening of the U.S. dollar and the Russian Central Bank’s reduction of currency rate support, have negatively affected the value of the Russian ruble relative to the U.S. dollar. Fluctuations in the rates at which the U.S. dollar are exchanged into Russian rubles may result in both foreign currency transaction and translation losses. We are subject to exchange rate fluctuations if we or one of our subsidiaries exchanges one currency into another, in order to conduct cross-border operations, and as we translate ruble denominated assets and liabilities that fluctuate from period-to-period. The former results in a transaction gain/loss that is reflected in our operating results. The latter results in a translation gain/loss reflected in other comprehensive income/loss in equity. Additionally, translation of historical operating results at average exchange rates for respective periods of time will also generate foreign currency translation adjustments that are reflected in our operating results. Presently, BioLab 612 and Panacela conduct most of their activities in Russia. As such we expect most of the foreign currency fluctuations to be related to accounting translations, versus transaction gains and losses.

Even before the current events mentioned above, and since the early 1990s, Russia has sought to transform from a one-party state with a centrally planned economy to a democracy with a market economy. As a result of the sweeping nature of various reforms and the failure of some of them, the political system of Russia remains vulnerable to popular

dissatisfaction, including demands for autonomy from particular regional and ethnic groups. Current and future changes in the Russian government, major policy shifts or lack of consensus between various branches of the government and powerful economic groups could disrupt or reverse economic and regulatory reforms. Furthermore, the Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, and has experienced periods of considerable instability. Although the Russian economy showed positive trends until 2008, including annual increases in the gross domestic product, a relatively stable currency, strong domestic demand, rising real wages and a reduced rate of inflation, these trends were interrupted by the global financial crisis in late 2008, in which

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Russia experienced adverse economic and financial effects including a substantial decrease in the growth rate of gross domestic product, depreciation of local currency and a decline in domestic and international demand for its products and services. Economic instability in Russia could materially adversely affect our business, financial condition and results of operations.

The current geopolitical instability arising from U.S relations with Russia, and related sanctions by the U.S. government against certain Russian companies and individuals, may have an adverse effect on us.

Political and economic relations between Russia and the U.S., two of the jurisdictions in which we operate, are complex. Recent situations involving Ukraine, Crimea, Iran, Syria, and alleged cyberespionage by the Russian government against the U.S. Democratic National Committee and in connection with the 2016 U.S. presidential election, along with the response of the governments of Russia, the U.S., member states of the E.U., the E.U. itself and other nations, have the potential to materially adversely affect our operations in Russia through a variety of situations. In particular, due to Russia's recent military intervention in Ukraine, the United States, Canada and the E.U. have imposed sanctions against Russian officials, certain Russian companies and individuals. These sanctions were designed to affect various elements of Russia's economy, with a particular focus on defense companies, individuals identified by the U.S. Department of State as being in the "inner circle" of the current Russian president, banks and energy companies. Russia has responded with certain countermeasures, including limiting the import of certain goods from the U.S. and other countries.

There can be no assurance that such sanctions will not be expanded more broadly to impact a greater variety of actors in the Russian economy. If the U.S. government significantly broadens the scope of sanctions against Russia to impose further political and economic costs, and/or the Russian government responds with further countersanctions, the operation of our direct and indirect Russian subsidiaries, BioLab 612 and Panacela Labs, LLC, which perform clinical development work under grants received from the MPT and have development or other intellectual property rights to certain of our drug candidates, may be materially and adversely affected. Furthermore, because our company is majority-owned by an investor with ties to Russia, and several Russian citizens and residents serve on our board of directors, our ability to secure and maintain contracts with the U.S. Department of Defense and other U.S. government agencies or departments, from which we received 69.0% and 35.4% of our revenues for the years ended December 31, 2017 and 2016, respectively, may become more difficult, which could cause a material adverse impact on our business, prospects, results of operation, and financial condition.

Emerging markets, such as Russia, are subject to greater risks than more developed markets and financial turmoil in Russia could disrupt our business.

Investors in emerging markets, such as Russia, should be aware that these markets are subject to greater risks than more developed markets, including significant economic risks. For example, the Russian economy has periodically experienced high rates of inflation. According to The World Bank, the annual inflation rate in Russia, as measured by the consumer price index, was 15.5% in 2015, 7.1% in 2016 and 3.7% in 2017. Periods of higher inflation may slow economic growth. Inflation also is likely to increase some of our costs and expenses including the costs for our Russian subsidiaries to conduct business operations, including any outsourced product testing costs.

Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set forth in our filings with the SEC about our operations in Russia may become outdated relatively quickly.

The legal system in Russia can create an uncertain environment for business activity, which could materially adversely affect our business and operations in Russia.

The legal framework in Russia is still under development and large portions of this framework have only recently become operational. The relatively recent enactment of many laws and the lack of consensus about the aims, scope, content, and pace of economic and political reforms have resulted in ambiguities, inconsistencies, and anomalies in the Russian legal system. The enforceability and underlying constitutionality of more recently enacted laws are in doubt, and many new laws remain untested.

As a result, its legal system can be characterized by: inconsistencies between and among laws and governmental, ministerial, and local regulations, orders, decisions, resolutions, and other acts; gaps in the regulatory structure resulting from the delay in adoption or absence of implementing regulations; selective enforcement of laws or

regulations, sometimes in ways that have been perceived as being motivated by political or financial considerations; limited judicial and administrative guidance on interpreting legislation; relatively limited experience of judges and courts in interpreting recent commercial legislation; a perceived lack of judicial and prosecutorial independence from political, social and commercial forces; inadequate court system resources; a high degree of discretion on the part of the judiciary and governmental authorities; and underdeveloped bankruptcy procedures that are subject to abuse.

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In addition, as is true of civil law systems generally, judicial precedents generally have no binding effect on subsequent decisions. Not all legislation and court decisions in Russia are readily available to the public or organized in a manner that facilitates understanding. Enforcement of court orders can in practice be very difficult. All of these factors make judicial decisions difficult to predict and effective redress uncertain. Additionally, court claims and governmental prosecutions may be used in furtherance of what some perceive to be political or commercial aims.

The untested nature of much of recent legislation in Russia and the rapid evolution of its legal system may result in ambiguities, inconsistencies, and anomalies in the application and interpretation of laws and regulations. Any of these factors may affect our ability to enforce our rights under our contracts or to defend ourselves against claims by others, or result in our being subject to unpredictable requirements. These uncertainties also extend to property rights and the expropriation or nationalization of any of our entities, their assets or portions thereof, potentially without adequate compensation, could materially adversely affect our business, financial condition and results of operations.

Judgments rendered by a court in any jurisdiction outside Russia are likely to be recognized by courts in Russia only if: (i) an international treaty providing for the recognition and enforcement of judgments in civil cases exists between Russia and the country where the judgment is rendered; and/or (ii) a federal law of Russia providing for the recognition and enforcement of foreign court judgments is adopted. No such federal law has been passed and no such treaty exists between the United States and Russia for the reciprocal enforcement of foreign courts' judgments. In the absence of an applicable treaty or convention providing for the recognition and enforcement of judgments in civil and commercial matters between the United States and Russia, a judgment of a U.S. court may be recognized and enforced in Russia only on the grounds of reciprocity. In each case, reciprocity must be established and, in the absence of a developed court practice, it is difficult to predict whether a Russian court will be inclined to recognize and enforce a U.S. court judgment on the grounds of reciprocity in any particular instance.

Changes in the tax system in Russia or the arbitrary or unforeseen application of existing rules could materially adversely affect our financial condition and results of operations.

There have been significant changes to the taxation system in Russia in recent years as the authorities have gradually replaced legislation regulating the application of major taxes such as corporate income tax, value added tax, corporate property tax, and other taxes with new legislation. Effective January 1, 2015, the Russian tax law was amended as part of the government's "deoffshorization" policy to, among other things, introduce a concept analogous to that of controlled foreign corporations found in other jurisdictions.

Tax authorities in Russia have also been aggressive in their interpretation of tax laws and their many ambiguities, as well as in their enforcement and collection activities. Technical violations of contradictory laws and regulations, many of which are relatively new and have not been subject to extensive application or interpretation, can lead to penalties. High-profile companies, particularly those operating in strategically sensitive sectors, can be perceived to be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. BioLab 612 and Panacela Labs, LLC's tax liabilities may become greater than the estimated amount that they have expensed to date and paid or accrued on the balance sheets, particularly if the tax benefits currently received in Russia are changed or removed. Any additional tax liability, as well as any unforeseen changes in tax laws, could materially adversely affect our future results of operations, financial condition or cash flows in a particular period.

In 2006, the Supreme State Commercial (Arbitrazh) Court of Russia issued a ruling that introduced the concept of an "unjustified tax benefit," which is a benefit that may be disallowed for tax purposes. Specific examples cited by the court include benefits obtained under transactions lacking a business purpose (i.e., when the only purpose of a deal or structure is to derive tax benefits). The tax authorities have actively sought to apply this concept when challenging tax positions taken by taxpayers. Although the intention of the ruling was to combat tax abuse, in practice there is no assurance that the tax authorities will not seek to apply this concept in a broader sense than may have been intended by the court. In addition, the tax authorities and the courts have indicated a willingness to interpret broadly the application of criminal responsibility for tax violations.

Russian transfer pricing laws allow the Russian tax authorities to make transfer pricing adjustments and impose additional tax liabilities with respect to "controlled" transactions (except for those conducted at state regulated prices and tariffs). The list of "controlled" transactions under the transfer pricing legislation includes transactions performed

with related parties and certain types of cross-border transactions. Special transfer pricing rules apply to transactions with securities and derivatives only if they fall in the scope of "controlled transactions". The burden of proving market prices rests with the taxpayer.

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The Russian Federation is actively involved in discussing measures against tax evasion by the use of low tax jurisdictions and aggressive tax planning structures. In this regard, the following rules and concepts in the Russian Tax Code may affect our business in Russia:

- Controlled Foreign Companies rules, pursuant to which undistributed profits of certain foreign organizations as well as foreign structures not being legal entities controlled by Russian tax residents should be subject to taxation in Russia;
- the concept of tax residency for legal entities whereby foreign legal entities would be deemed Russian tax residents if their place of management is located in Russia; and
- beneficial ownership concept which provides that treaty relief should be available to foreign legal entities which qualify for the beneficial owners of income.

Implementation of the aforementioned new rules and concepts and some other tax anti-avoidance initiatives may impose additional administrative burden on us. No assurance can be given as to the practical application of these new rules and concepts by the Russian tax authorities and, consequently, their potential impact including additional tax liability, if any on us.

Actions by the tax authorities in Russia may result in the sudden imposition of arbitrary or onerous taxes on our operations in Russia.

BioLab 612 and Panacela Labs, LLC’s tax liabilities are subject to periodic tax inspections that may result in tax assessments, penalties and interest being claimed from such subsidiaries for prior tax periods. Generally, tax declarations of Russian subsidiaries remain open and subject to audit by tax and/or customs authorities for three calendar years immediately preceding the year in which the decision to conduct an audit is taken. However, the fact that a particular year has been reviewed by tax authorities does not preclude that year from further review or audit during the eligible three-year limitation period by a superior tax authority. Moreover, the Russian tax authorities are allowed to carry out repeat field tax audits in connection with the restructuring or liquidation of a taxpayer or if the taxpayer resubmits an adjusted tax return based on which the amount of tax is reduced. The limitation of the tax audit period corresponds to the statute of limitations on the commission of a tax offense, which is also limited to three years from the date on which a tax offense was committed or from the date following the end of the tax period during which the tax offense was committed depending on the nature of the tax offense. The Russian Tax Code provides for the extension of the three-year statute of limitations if the actions of the taxpayer created insurmountable obstacles for the tax audit.

As none of the relevant terms are defined, tax authorities may have broad discretion to argue that a taxpayer has "obstructed", "hindered," or "created insurmountable obstacles" with respect to an inspection and may ultimately seek to review and possibly to apply penalties beyond the three-year term. Further, there is no guarantee that the tax authorities will not review compliance with applicable tax law beyond the three-year limitation period. Tax audits may result in additional costs if the relevant authorities conclude that the BioLab 612, Panacela Labs, LLC, or both did not satisfy their tax obligations in any given year. The outcome of these audits may result in significant fines, penalties and enforcement measures which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

The tax system in Russia imposes additional burdens and costs on our operations there and complicate our tax planning and related business decisions. For example, the tax environment in Russia has historically been complicated by contradictions in Russian tax law and ambiguity in areas such as the deductibility of certain expenses. This uncertainty could result in a greater than expected tax burden and potentially exposes us to significant fines and penalties and enforcement measures, despite our best efforts at compliance. These factors raise the risk of a sudden imposition of arbitrary or onerous taxes on our operations in Russia. This could materially adversely affect our financial condition and results of operations.

Selective or arbitrary government action may have an adverse effect on our business.

Government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify, or terminate contracts. Selective or arbitrary

actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

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Shareholder liability under Russian legislation could cause us to become liable for the obligations of our subsidiaries. Under Russian law, we may become liable for the obligations of our Russian subsidiaries if it was determined that: (i) we had the ability to make, or exert influence on, decisions for such subsidiaries as a result of our equity interest, the terms of a binding contract with such Russian subsidiary or in any other way; and (ii) the relevant Russian subsidiary concluded the transaction giving rise to the obligations pursuant to the Company's instructions or consent. In addition, we may have secondary liability for the obligations of our Russian subsidiaries in a situation where the respective Russian subsidiary becomes insolvent or bankrupt and this was a result of, or was otherwise attributable to, actions of the Company. This type of liability could result in significant losses, and could have a material adverse effect on the Company’s business, results of operations or financial position.

Accordingly, in the Company’s position as a parent Biolab 612 and Panacela, there is a risk that it could be held liable in certain limited circumstances for the debts of its effective subsidiaries. If this liability is significant, it could materially adversely affect our business and our results of operations.

Russia may depart from its international obligations in exceptional circumstances

In July 2015 the Constitutional Court of the Russian Federation issued a resolution which introduced a mechanism for Russian state bodies to avoid enforcement of decisions of the European Court of Human Rights ("ECHR") in cases where such enforcement would contradict the Constitution of the Russian Federation.

Namely, if a Russian court or other governmental body comes to a conclusion that a resolution of the ECHR, which is to be enforced by a Russian court / governmental body, is grounded on an interpretation of the European Convention on Human Rights which leads to contradiction with the Constitution of the Russian Federation - such court/body must apply to the Constitutional Court which will finally determine whether enforcement is permissible or not.

The resolution creates a risk for businesses and persons who might seek legal recourse from the ECHR after failing to receive remedy in all Russian instances, despite the fact that Russia signed and ratified the European Convention of Human Rights.

In addition, there is a risk that such interpretation could be extended to other obligations of Russia in the area of international law. Thus, we might face difficulties enforcing Russian awards obtained from other intergovernmental institutions or tribunals if Russian state authorities consider that award to be grounded on an interpretation of international treaties that is contrary to the norms of the Constitution of the Russian Federation.

Our Russian operating entities can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.

BioLab 612 and Panacela Labs, LLC were organized under the laws of Russia. Certain provisions of Russian law may allow a court to order the liquidation of a locally organized legal entity on the basis of its formal noncompliance with certain requirements during formation, reorganization, or during its operations. Additionally, Russian corporate law allows the government to liquidate a company if its net assets fall below a certain threshold. Similarly, there have also been cases in Russia in which formal deficiencies in the establishment process of a legal entity or noncompliance with provisions of law have been used by courts as a basis for liquidation of a legal entity. Weaknesses in the legal systems of Russia create an uncertain legal environment, which makes the decisions of a court or a governmental authority difficult, if not impossible, to predict. If involuntary liquidation of either of the aforementioned entities were to occur, such liquidation could materially adversely affect our financial condition and results of operations.

Crime and corruption could disrupt our ability to conduct our business.

Political and economic changes in Russia in recent years have resulted in significant dislocations of authority. The local and international press has reported the existence of significant organized criminal activity, particularly in large metropolitan centers. In addition, the local and international press has reported high levels of corruption, including the bribing of officials for the purpose of initiating investigations by government agencies. Press reports have also described instances in which state officials have engaged in selective investigations and prosecutions to further the interests of the state and individual officials, as well as private businesses, including competitors and corporate raiders. Corruption in Russia is perceived to be pervasive and, in some cases, worsening. The government in Russia has recently pursued a campaign against corruption. However, there is no assurance that such laws or other laws enacted elsewhere will be applied with any effectiveness by the local authorities and the continuing effects of corruption, money laundering and other criminal activity could have a negative effect on the Russian economy and

could materially adversely affect our business in Russia.

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Risks Relating to our Securities

Our principal stockholder has the ability to control our business, which may be disadvantageous to other stockholders.

As of the date of this filing, Mr. David Davidovich, a venture capital investor, beneficially owns or controls approximately 57.3% of the voting power of our outstanding common stock. As a result of his ability to control a majority of the voting power of our outstanding common stock, Mr. Davidovich has the ability to control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. Additionally, we granted Mr. Davidovich contractual rights to choose a majority of the directors nominated for election by our Board. Mr. Davidovich may have interests that are different from those of other stockholders and may vote in a way with which other stockholders disagree and that may be adverse to other stockholders' interests. Moreover, this concentration of share ownership makes it impossible for other stockholders to replace directors and management without the consent of Mr. Davidovich. In addition, this significant concentration of share ownership may adversely affect the price at which prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders and may have the effect of delaying, preventing, or deterring a change of control of the Company and could deprive our stockholders of an opportunity to receive a premium for their company stock as part of a sale of the Company. Additionally, our corporate structure, including the ownership of Mobilan in Panacela, may deter third parties from entering into collaboration and licensing arrangements with us.

We are a "controlled company" within the meaning of the NASDAQ rules and, as a result, qualify for and rely upon exemptions from certain corporate governance requirements. Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Because Mr. Davidovich holds common stock that represents a majority of the voting power of our outstanding common stock, we may be considered a "controlled company" within the meaning of the NASDAQ corporate governance standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, group, or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements that:

- a majority of the board of directors consist of independent directors;
- we have a nominating and corporate governance committee that is composed entirely of independent directors; and
- we have a compensation committee that is composed entirely of independent directors.

We are currently utilizing these exemptions and therefore, we do not offer the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

There is uncertainty regarding the application of the federal and state securities laws to our February 2015 offering of common stock and warrants, and there is a corresponding risk that we could be required to refund the purchase price of securities offered to purchasers who so elect.

We conducted an offering under a registration statement filed with the Securities and Exchange Commission ("SEC") and a concurrent private placement intended to comply with the requirements of Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder. Shares of common stock and warrants were offered and sold in combination. The shares of common stock and Series B pre-funded warrants were intended to be offered and sold in a transaction registered under the Securities Act, while the other warrants and shares of common stock issuable thereunder were intended to be offered and sold in a private placement exempt from the registration requirements of the Securities Act.

While we are aware of other transactions using a concurrent public/private offering approach, the SEC has not addressed whether concurrent public and private offerings and sales to the same prospective investors would adversely impact the public offering or preclude the private offering from satisfying the requirements of Rule 506(b). If the securities offered in our concurrent private placement do not satisfy the conditions of Rule 506(b), the offering would be a violation of Section 5 of the Securities Act and each purchaser would have the right to rescind its purchase of the securities, meaning that we would be required to refund the purchase price of the securities to each purchaser electing rescission. If that were to occur, we would face severe financial demands and reputational harm that could adversely affect our business and operations. Additionally, if we did not in fact qualify for the exemptions upon which it has

relied, we may become subject to significant fines and penalties imposed by SEC. It is also possible that additional remedies may be available to purchasers under applicable state law.

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The price of our common stock has been and could remain volatile, which may in turn expose us to securities litigation.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 1, 2016 through December 31, 2017, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $5.55 per share in the second quarter of 2017 to a low of $1.22 in the fourth quarter of 2016. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent, and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility in addition to volatility caused by the occurrence of industry and company specific events. Factors that could cause fluctuations include, but are not limited to, the following:

- our progress in developing and commercializing our products;
- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- major catastrophic events;
- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our product candidates, including results of our preclinical studies and clinical trials;
- status of contract and funding negotiations relating to our product candidates;
- events affecting our collaborators;
- events affecting our competitors;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the U.S. and other countries;
- failure of our common stock to be listed or quoted on the NASDAQ Capital Market, another national market system, or any national stock exchange;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock market in general, and the stock price of companies listed on the NASDAQ, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of actual operating performance.

As a result of the volatility of our stock price, we could be subject to securities litigation, which could result in substantial costs and divert management’s attention and company resources from our business.

Issuance of additional equity may adversely affect the market price of our stock.

We are currently authorized to issue 25,000,000 shares of common stock and 1,000,000 shares of preferred stock. As of this filing, 11,279,834 shares of our common stock were issued and outstanding, we had outstanding warrants to purchase 710,174 shares of our common stock at an average exercise price of $8.95 per share, and options to purchase 211,487 shares of our common stock at an average exercise price of $36.94 per share. To the extent we issue shares of common stock or our outstanding options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any other future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, certain of our outstanding warrants contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such securities to increase and/or the exercise price of such warrants to decrease.

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Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve, or wind up our business and other terms. If we issue additional shares of preferred stock in the future that have preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Additionally, the conversion of any preferred stock issued in the future into our common stock could result in significant dilution to the holders of our common stock.

The eventual public resale by certain of our significant stockholders could have a negative effect on the trading price of our common stock.

In July 2015, we issued an aggregate of 6,716,163 shares of our Company's common stock to Mr. Davidovich and Rusnano. The issuances of these shares were not registered under the Securities Act of 1933, and the shares are only able to be resold pursuant to a separate registration statement or an applicable exemption from registration (under both federal and state securities laws). Contractual restrictions prohibiting Mr. Davidovich from selling his shares have expired and pursuant to the terms of registration rights agreements entered into between the Company and each of Mr. Davidovich and Rusnano, we have filed a registration statement on Form S-3 with the SEC to register the public offer and resale of the shares held by these stockholders. The registration statement has been declared effective by the SEC and Mr. Davidovich and Rusnano are each able to freely sell some or all of their shares of our Company's common stock. If all or a substantial portion of these shares are resold into the public markets under such registration statement or otherwise, such transactions may cause a decline in the trading price of our common stock.

We do not intend to pay dividends for the foreseeable future.

We do not intend to declare or pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We also consider from time to time various strategic alternatives that could involve issuances of additional shares of common stock or shares of preferred stock, including but not limited to acquisitions and business combinations.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these reports and we currently do not have any industry analysts covering us. In the event we do regain analyst coverage, there can be no assurance that analysts will provide favorable coverage. Our stock price may be adversely impacted by our current lack of analyst coverage as we may have less visibility in the financial markets than other companies in our industry, which may cause declined trading volume and stock price.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Properties

Our corporate headquarters is located at 73 High Street, Buffalo, New York 14203. We have approximately 32,000 square feet of laboratory and office space under a twelve-year lease through June of 2019 with successive two-year renewals, of which approximately 9,685 square feet was subleased to various companies. The subleases covering the majority of the subleased space may be terminated by either party upon 30 days written notice to the other party. This space serves as our corporate headquarters and U.S. corporate headquarters for Panacela. In addition, we have approximately 736 square feet under lease outside of the U.S. expiring at varying times through 2018. We do not own any real property.

Item 3. Legal Proceedings

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In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows, or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters as of December 31, 2017, that in the opinion of management might have a material adverse effect on our financial position, results of operations, or cash flows, or that are required to be disclosed under the rules of the SEC.

Item 4. Mine Safety Disclosure

None.

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PART II

Item 5: Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

STOCK EXCHANGE LISTING

Our common stock trades on The NASDAQ Capital Market under the symbol "CBLI." We have not paid dividends on our common stock. We currently intend to retain all future income for use in the operation of our business and for future stock repurchases and, therefore, we have no plans to pay cash dividends on our common stock at this time.

STOCK PRICES

The following table sets forth the range of high and low sale prices on The NASDAQ Capital Market, for each quarter during 2017 and 2016. On March 5, 2018, the last reported sale price of our common stock was $3.60 per share.

2017	High	Low
First Quarter	$2.06	$1.35
Second Quarter	5.55	1.42
Third Quarter	3.69	2.32
Fourth Quarter	4.25	2.24
2016		
First Quarter	$4.00	$2.42
Second Quarter	3.30	1.92
Third Quarter	3.25	1.55
Fourth Quarter	1.96	1.22

STOCKHOLDERS

As of March 5, 2018, there were approximately 29 stockholders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

DIVIDENDS

We have never declared or paid any cash dividends on our capital stock. We currently intend to use the net proceeds from any offerings of our securities and our future earnings, if any, to finance the further development and expansion of our business and do not intend or expect to pay cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness, and plans for expansion and restrictions imposed by lenders, if any.

UNREGISTERED SALE OF SECURITIES

We did not sell any equity securities during the fiscal year ended December 31, 2017 in transactions that were not registered under the Securities Act.

ISSUER PURCHASES OF EQUITY SECURITIES

We made no repurchases of our securities during the year ended December 31, 2017.

Item 6: Selected Financial Data

Not required for smaller reporting company filers.

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

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OVERVIEW

We are an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. During the two years ended December 31, 2017, we conducted business in the U.S. and Russia through two subsidiaries, one of which is wholly owned, BioLab 612; one of which is owned in collaboration with a financial partner, Panacela. In addition, we conducted business with a former subsidiary, Incuron, which will pay us a 2% royalty on future commercialization, licensing, or sale of certain technology we sold to Incuron. See Item 1, "Business" for more information on our product candidates and our strategic partnerships.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues, and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, income taxes, stock-based compensation, investments, and in-process R&D. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectability is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. We generate our revenue from two different types of contractual arrangements: (i) cost-reimbursable grants and contracts and (ii) fixed-price grants and contracts. Costs consist primarily of actual internal labor charges, subcontractor and material costs incurred, plus an allocation of fringe benefits, overhead and general and administrative expenses ("G&A"), and applicable fees, if any, based on the terms of the contract.

Revenues on cost-reimbursable grants and contracts are recognized in an amount equal to the costs incurred during the period, plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract: if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned. Otherwise, we compute fee income earned in a given period by using a proportional performance method based on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the grant or contract.

Revenues on fixed-price grants and contracts are recognized using a percentage-of-completion method, which uses assumptions and estimates, as appropriate. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-price grant or contract to determine levels of accomplishments throughout the life of the grant or contract.

Stock-Based Compensation

We expense all share-based awards to employees and consultants, including grants of stock options and shares, based on their estimated fair value at the date of grant. Costs of all share-based payments are recognized over the requisite service period that an employee or consultant must provide to earn the award (i.e., the vesting period) and allocated to the functional operating expense associated with that employee or consultant.

Fair Value of Financial Instruments

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The carrying value of cash and cash equivalents, accounts receivable, short-term investments, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock warrants, which are classified as liabilities, are recorded at their fair market value as of each reporting period.
The measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.
- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 – Instruments where significant value drivers are unobservable to third parties.

We use the Black-Scholes model to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 3. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life of the warrants; (iii) the expected volatility using a weighted-average of historical volatilities of CBLI and a group of comparable companies; and (iv) the risk-free market rate.
As of December 31, 2017, we held approximately $1.0 million in accrued expenses classified as Level 3 securities for warrants to purchase common stock.

Income Taxes

Determining the consolidated provision for income tax expense, deferred tax assets and liabilities and related valuation allowance, if any, involves judgment. On an on-going basis, we evaluate whether a valuation allowance is needed to reduce our deferred income tax assets to an amount that is more likely than not to be realized. The evaluation process includes assessing historical and current results in addition to future expected results. Upon determining that we would be able to realize our deferred tax assets, an adjustment to the deferred tax valuation allowance would increase income in the period we make such determination.

Research and Development Expenses

R&D costs are expensed as incurred. Advance payments are deferred and expensed as performance occurs. R&D costs include the cost of our personnel consisting of salaries, incentive and stock-based compensation, out-of-pocket preclinical and clinical trial costs usually associated with CROs, drug product manufacturing and formulation, and a pro-rata share of facilities expense and other overhead items.

General and Administrative Expenses

G&A functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. The specific costs include the cost of our personnel consisting of salaries, incentive and stock-based compensation, out-of-pocket costs usually associated with attorneys (both corporate and intellectual property), bankers, accountants and other advisors, and a pro-rata share of facilities expense and other overhead items.

Other Income and Expenses

Other recurring income and expenses primarily consists of interest income on our investments, changes in the market value of our derivative financial instruments, gains and losses on disposal of fixed assets, and foreign currency transaction gains or losses.

YEAR ENDED DECEMBER 31, 2017 COMPARED TO YEAR ENDED DECEMBER 31, 2016

Revenue

Revenue decreased from $3.5 million for the year ended December 31, 2016 to $1.9 million for the year ended December 31, 2017, representing a decrease of $1.6 million, or 45%, primarily due to the completion of our grants from the MPT at December 31, 2016, which resulted in a revenue reduction of $1.7 million. Revenue from the DoD under the JWMRP contract for continued preclinical development along with other drug manufacturing activities increased $0.1 million during 2017 and should continue to increase in 2018 as the in-progress contracted research activities to compare the historical drug formulation used in prior

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preclinical and clinical studies versus the to-be-marketed drug product lots of entolimod submitted for approval under CBLI's application for pre-EUA are expected to be completed. Revenue from both the JWMRP contract and the PRMRP grant is expected to increase as a result of the commencement of contracted tasks critical for the preparation of a BLA of entolimod as a MRC. Service revenue from Incuron is expected to continue into 2018 in an amount similar to 2017.

Since these revenue sources are cost reimbursable in nature, variances in these activities, period to period, are directly aligned with variances in the underlying costs of service. Differences in our revenue sources, by program, between the years are set forth in the following table:

		Year Ended December 31,							
Funding Source	Program	2017	Percent of Total		2016	Percent of Total		Variance	
DoD	JWMRP Contract	$1,337,392	68.6	%	$1,198,247	34.1	%	$139,145	
DoD	PRMRP Grant	5,075	0.3	%	49,077	1.4	%	(44,002	)
DoD	DTRA Contract	1,886	0.1	%	—	—	%	1,886	
MPT[(1)]	CBLB612	—	—	%	304,485	8.7	%	(304,485	)
MPT[(1)]	Entolimod oncology	—	—	%	734,194	20.9	%	(734,194	)
Incuron	Service Contracts	604,009	31.0	%	622,360	17.7	%	(18,351	)
		1,948,362	100.0	%	2,908,363	82.7	%	(960,001	)
MPT[(1)]	Mobilan	—	—	%	610,039	17.3	%	(610,039	)
		$1,948,362	100.0	%	$3,518,402	100.0	%	$(1,570,040	)

(1) The contracts received from Russian government entities are denominated in Russian rubles. The revenue above was calculated using average exchange rates for the periods presented.

We anticipate our revenue over the next year will continue to be derived primarily from government grants and contracts and service contracts from Incuron. The following table sets forth information regarding our currently active grant contracts as of December 31, 2017:

Funding source	Program	Total award value	Funded award value	Cumulative revenue recognized	Funded backlog	Unfunded backlog
DoD	JWMRP Contract	$9,226,455	$9,226,455	$2,728,855	$6,497,600	$ —
DoD	PRMRP Grant	6,573,992	6,573,992	74,326	6,499,666	—
MPT[(1)]	CBLB612	3,342,247	3,342,247	3,342,247	—	—
MPT[(1)]	Entolimod oncology	3,035,575	3,035,575	3,035,575	—	—
		22,178,269	22,178,269	9,181,003	12,997,266	—
MPT[(1)]	Mobilan	3,207,585	3,207,585	3,207,585	—	—
		$25,385,854	$25,385,854	$12,388,588	$12,997,266	$ —

(1) The contract values above are calculated based on the cumulative revenue recognized to date plus our backlog valued at the December 31, 2017 exchange rate for Russian ruble denominated values.

Research and Development Expenses

R&D expenses decreased from $6.50 million for the year ended December 31, 2016 to $5.05 million for the year ended December 31, 2017, representing a decrease of $1.45 million, or 22%. Variances in individual development programs are noted in the table below. Significant reductions include the $1.4 million reduction of funds spent on Entolimod for oncology indication due to the completion of a clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naive patients with primary colorectal cancer, the $0.46 million reduction in spending related to CBLB612 due to the completion of a clinical study in patients with breast cancer receiving doxorubicin-cyclophosphamide chemotherapy, and the $0.25 million reduction in Panacela product candidate spending due to the completion of the active recruitment stage of the ongoing clinical studies with Mobilan. These reductions were partially offset by increased expenses on Entolimod 's biodefense indication for continued preclinical development along with other drug manufacturing activities associated with our JWMRP contract and expenses associated with our regulatory efforts with the EMA to prepare a pediatric investigational plan and other activities in

support of filing a MAA with EMA. We expect that costs associated with entolimod's biodefense indication to significantly increase in 2018 as activity associated with our DoD contract and regulatory efforts with the EMA and FDA will continue to ramp up. Curaxins expenditures are expected to increase as ongoing clinical trials will continue to enroll in 2018. Panacela product candidates

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are expected to decrease as we complete ongoing clinical trials in 2018. CBLB612 and entolimod for oncology indication expenditures are expected to decrease while we evaluate clinical and preclinical study data to determine further development plans which optimize shareholder value.

	Year Ended December 31,		
	2017	2016	Variance
Entolimod's biodefense indication	$3,971,447	$3,328,865	$642,582
CBLB612	25,611	484,238	(458,627)
Entolimod's oncology indications	310,655	1,716,542	(1,405,887)
	4,307,713	5,529,645	(1,221,932)
Curaxins	492,992	466,684	26,308
Panacela product candidates	247,718	499,793	(252,075)
Total research & development expenses	$5,048,423	$6,496,122	$(1,447,699)

General and Administrative Expenses

G&A expenses decreased from $3.4 million for the year ended December 31, 2016 to $2.5 million for the year ended December 31, 2017, representing a decrease of $0.9 million, or 26.0%. These reductions consisted primarily of a reduction of $0.4 million in compensation expense due to fewer personnel, a reduction of $0.2 million in fees incurred in relation to the treasury stock repurchase in 2016, and a reduction of $0.2 million in other operating expenses primarily related to the reduction in the idle facility reserve as a result of the passage of time and ability to sublet additional space at higher rates.

Other Income and Expenses

Other income and expense decreased from $3.8 million of other income for the year ended December 31, 2016 to other expense of $4.2 million for the year ended December 31, 2017, representing an expense increase of $8.0 million or 213%. This expense increase was primarily related to a $7.5 million variance related to our warrant liability, and a $0.4 million variance in our foreign currency exchange gains and losses.

Liquidity and Capital Resources

We incurred net losses of $160.4 million from our inception through December 31, 2017. Historically, we have not generated, and do not expect to generate revenue from sales of product candidates in the immediate future. Since our founding in 2003, we have funded our operations through a variety of means:

- From inception through December 31, 2017, we have raised $144.7 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $7.3 million in net proceeds from the issuance of long-term debt instruments;
- DoD and the Biomedical Advanced Research and Development Authority (within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services) have funded grants and contracts totaling $60.4 million for the development of entolimod for its biodefense indication;
- The Russian Federation has funded a series of contracts totaling $17.3 million, based on the exchange rates in effect on the date of funding. These contracts include requirements for us to contribute matching funds, which we have satisfied or expect to satisfy with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses;
- We have been awarded $4.0 million in grants and contracts not described above, all of which has been recognized at December 31, 2017;
- Incuron was formed to develop and commercialize the Curaxins product line, including its lead oncology drug candidate CBL0137. We sold our remaining ownership interest in Incuron during 2015 for approximately $4.0 million and retain a 2% royalty interest in the CBL0137 technology; and
- Panacela was formed to develop and commercialize preclinical compounds, which were transferred to Panacela through assignment and lease agreements. Rusnano contributed $9.0 million and we contributed $3.0 million plus intellectual property at formation. As of the date of this filing, CBLI owns 67.57% of Panacela.

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We have incurred cumulative net losses and expect to incur additional losses related to our R&D activities. We do not have commercial products and have limited capital resources. As of December 31, 2017 we had $8.8 million in cash, cash equivalents and short-term investments which, along with the active government contracts described above, are expected to fund our projected operating requirements and allow us to fund our operating plan, in each case, for at least 12 months beyond the filing date of this Annual Report on Form 10-K. However, until we are able to commercialize our product candidates at a level that covers our cash expenses, we will need to raise substantial additional capital, which we may be unable to raise in sufficient amounts, when needed and at acceptable terms. Our plans with regard to these matters may include seeking additional capital through debt or equity financing in public or private transactions, the sale or license of drug candidates, or obtaining additional research funding from the U.S. or Russian governments. There can be no assurance that we will be able to obtain future financing on acceptable terms, or that we can obtain additional government financing for our operations. If we are unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

Operating Activities

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2016:

	For the year ended December 31,		
	2017	2016	Variance
Net cash used in operating activities	$(6,611,459)	$(5,039,639)	$(1,571,820)
Net cash provided by investing activities	3,887,891	5,673,013	(1,785,122)
Net cash provided by financing activities	—	539,998	(539,998)
Effect of exchange rate change on cash and equivalents	52,300	(189,980)	242,280
Increase (decrease) in cash and cash equivalents	(2,671,268)	983,392	(3,654,660)
Cash and cash equivalents at beginning of period	6,901,816	5,918,424	983,392
Cash and cash equivalents at end of period	$4,230,548	$6,901,816	$(2,671,268)

Operating Activities

Net cash used in operations increased by $1.6 million to $6.6 million for the year ended December 31, 2017 from $5.0 million for the year ended December 31, 2016. Net cash used in operating activities for the period ending December 31, 2017 consisted of a reported net loss of $9.8 million, which was partially offset by $4.4 million of net non-cash operating activities, and further decreased by $1.2 million due to changes in operating assets and liabilities. The $4.4 million of net non-cash operating activities consisted principally of changes in the valuation of our warrant liability. Of the net $1.2 million change in operating assets and liabilities, $0.2 million was due to a net increase in accounts receivable, and $1.0 million was due to a net decrease in accrued expenses and accounts payable due to a reduction in clinical studies supported by completed MPT contracts and CMC activities associated with the DoD contract. Net cash used in operating activities for the period ending December 31, 2016 consisted of reported net loss of $2.6 million, which was further decreased by $3.2 million of net non-cash operating activities, and partially offset by a $0.8 million net increase due to changes in operating assets and liabilities. The net non-cash operating activities of $3.2 million consisted principally of changes in the valuation of our warrant liability and gains from equipment sales. Of the net $0.8 million change in operating assets and liabilities, $0.5 million was due to a net decrease in accounts receivable and other current assets due to a decrease in our MPT contracts and amortization of prepaid insurance, and $0.3 million was due to a net increase in accrued expenses and accounts payable primarily due to expense increases associated with clinical studies that were supported by completed MPT contracts, preclinical and other drug manufacturing activities, partially offset by reductions in personnel and outside professional fees.

Investing Activities

Net cash provided by investing activities decreased by $1.8 million to $3.9 million for the year ended December 31, 2017 from $5.7 million for the year ended December 31, 2016. The net cash provided by investing activities for the year ended December 31, 2017 consisted primarily of the net maturities of short-term investments. The net cash provided by investing activities for the year ended December 31, 2016 consisted primarily of net maturities of

short-term investments amounting to $5.5 million, and $0.2 million proceeds from the sale of equipment.

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Financing Activities

Cash provided by financing activities decreased by $0.5 million to $0.0 million for the year ended December 31, 2017 from $0.5 million for the year ended December 31, 2016. Net cash provided by financing activities for the year ended December 31, 2016 consisted of the sale of $0.5 million in treasury stock.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements at December 31, 2017.

Item 7A: Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting company filers.

Item 8: Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Board of Directors and
Stockholders of Cleveland BioLabs, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cleveland BioLabs, Inc. and Subsidiaries (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows, for each of the years in the two-year period ended December 31, 2017, and the related notes and schedules (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Meaden & Moore, Ltd.

MEADEN & MOORE, Ltd.

We have served as the Company’s auditor since 2005.

Cleveland, Ohio
March 6, 2018

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$4,230,548	$6,901,816
Short-term investments	4,561,357	8,343,657
Accounts receivable	554,468	352,700
Other current assets	233,617	289,768
Total current assets	9,579,990	15,887,941
Equipment, net	18,588	37,376
Other long-term assets	30,684	30,553
Total assets	$9,629,262	$15,955,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$201,396	$336,435
Accrued expenses	970,547	1,823,235
Accrued warrant liability	1,041,455	949,419
Total current liabilities	2,213,398	3,109,089
Non-current liabilities	7,494	—
Commitments and contingencies	—	—
Total liabilities	2,220,892	3,109,089
Stockholders' equity:		
Preferred stock, $.005 par value; 1,000,000 and 10,000,000 shares authorized as of December 31, 2017 and December 31, 2016, respectively, 0 shares issued and outstanding as of December 31, 2017 and December 31, 2016	—	—
Common stock, $.005 par value; 25,000,000 and 160,000,000 shares authorized as of December 31, 2017 and December 31, 2016, respectively, 11,279,834 and 10,987,166 shares issued and outstanding as of December 30, 2017 and December 31, 2016, respectively	56,395	54,932
Additional paid-in capital	163,106,400	158,773,753
Other comprehensive loss	(516,457)	(564,559)
Accumulated deficit	(160,446,612)	(150,740,156)
Total Cleveland BioLabs, Inc. stockholders' equity	2,199,726	7,523,970
Noncontrolling interest in stockholders' equity	5,208,644	5,322,811
Total stockholders' equity	7,408,370	12,846,781
Total liabilities and stockholders' equity	$9,629,262	$15,955,870

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2017	2016
Revenues:		
Grants and contracts	$1,948,362	$3,518,402
Operating expenses:		
Research and development	5,048,423	6,496,122
General and administrative	2,500,749	3,378,130
Total operating expenses	7,549,172	9,874,252
Loss from operations	(5,600,810)	(6,355,850)
Other income (expense):		
Interest and other income	197,766	263,653
Foreign exchange gain (loss)	(13,482)	362,140
Gain on investment provision	—	40,517
Change in value of warrant liability	(4,426,146)	3,099,481
Total other income (expense)	(4,241,862)	3,765,791
Net loss	(9,842,672)	(2,590,059)
Net loss (gain) attributable to noncontrolling interests	136,216	(68,806)
Net loss attributable to Cleveland BioLabs, Inc.	$(9,706,456)	$(2,658,865)
Net loss available to common stockholders per share of common stock, basic and diluted	$(0.87)	$(0.24)
Weighted average number of shares used in calculating net loss per share, basic and diluted	11,192,435	10,987,166

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Year Ended December 31,	
	2017	2016
Net loss including noncontrolling interests	$(9,842,672)	$(2,590,059)
Other comprehensive income (loss):		
Unrealized gain on short-term investments	362	3,904
Foreign currency translation adjustment	69,789	(158,537)
Comprehensive loss including noncontrolling interests	(9,772,521)	(2,744,692)
Comprehensive loss (gain) attributable to noncontrolling interests	114,167	(63,448)
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$(9,658,354)	$(2,808,140)

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(9,842,672)	$(2,590,059)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	21,081	63,456
Unrealized currency gain on short-term investments	(54,551)	(43,931)
Gain on equipment disposal	(6,727)	(180,901)
Investment loss provision	—	43,524
Non-cash compensation	—	13,623
Change in value of warrant liability	4,426,146	(3,099,481)
Changes in operating assets and liabilities:		
Accounts receivable	(201,768)	300,762
Other current assets	57,325	174,717
Other long-term assets	—	(3,736)
Accounts payable	(138,578)	124,006
Deferred revenue	2,285	(12,929)
Accrued expenses	(874,000)	171,310
Net cash used in operating activities	(6,611,459)	(5,039,639)
Cash flows from investing activities:		
Purchase of short-term investments	(8,631,685)	(17,225,557)
Sale of short-term investments	12,515,024	22,712,480
Proceeds from sale of equipment	8,956	198,914
Purchase of equipment	(4,404)	(10,249)
Decrease in restricted cash	—	(2,575)
Net cash provided by investing activities	3,887,891	5,673,013
Cash flows from financing activities:		
Net proceeds from sale of treasury stock	—	539,998
Net cash provided by financing activities	—	539,998
Effect of exchange rate change on cash and equivalents	52,300	(189,980)
Increase (decrease) in cash and cash equivalents	(2,671,268)	983,392
Cash and cash equivalents at beginning of period	6,901,816	5,918,424
Cash and cash equivalents at end of period	$4,230,548	$6,901,816
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$—	$—
Supplemental schedule of non-cash financing activities:		
Cashless exercise of warrants	$4,334,110	$—

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Treasury Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2015	10,987,166	$54,932	158,900	$(544,853)	$158,764,985
Stock based compensation	—	—	—	—	13,623
Sale of treasury stock	—	—	(158,900)	544,853	(4,855)
Increased ownership of Panacela Labs, Inc.	—	—	—	—	—
Net income (loss)	—	—	—	—	—
Unrealized gain on short-term investments	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at December 31, 2016	10,987,166	54,932	—	—	158,773,753
Exercise of warrants	292,688	1,463	—	—	4,332,647
Net loss	—	—	—	—	—
Unrealized gain on short-term investments	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at December 31, 2017	11,279,854	$56,395	—	$—	$163,106,400

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2015	$ (408,051)	$(147,978,831)	$ 5,149,670	$15,037,852
Stock based compensation	—	—	—	13,623
Sale of treasury stock	—	—	—	539,998
Increased ownership of Panacela Labs, Inc.	(7,233)	(102,460)	109,693	—
Net income (loss)	—	(2,658,865)	68,806	(2,590,059)
Unrealized gain on short-term investments	3,904	—	—	3,904
Foreign currency translation	(153,179)	—	(5,358)	(158,537)
Balance at December 31, 2016	(564,559)	(150,740,156)	5,322,811	12,846,781
Exercise of warrants	—	—	—	4,334,110
Net loss	—	(9,706,456)	(136,216)	(9,842,672)
Unrealized gain on short-term investments	362	—	—	362
Foreign currency translation	47,740	—	22,049	69,789
Balance at December 31, 2017	$ (516,457)	$(160,446,612)	$ 5,208,644	$7,408,370

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Cleveland BioLabs, Inc. ("CBLI" or the "Company") is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor ("TLR") activators has applications in radiation protection and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a medical radiation countermeasure and an immunotherapy for oncology and other indications.

CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. CBLI conducts business in the United States ("U.S.") and in the Russian Federation ("Russia") through two subsidiaries: one wholly owned subsidiary, BioLab 612, LLC ("BioLab 612"), which began operations in 2012; and Panacela Labs, Inc. ("Panacela"), which was formed by us and Joint Stock Company RUSNANO ("Rusnano"), our financial partner in the venture, in 2011. Unless otherwise noted, references to the "Company," "we," "us" and "our" refer to Cleveland BioLabs, Inc. together with its subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of CBLI, BioLab 612, and Panacela. All significant intercompany balances and transactions have been eliminated in consolidation. These financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Of the $4.2 million and $6.9 million of cash and cash equivalents at December 31, 2017 and December 31, 2016, respectively, $3.6 million and $2.4 million, respectively, consisted of highly liquid investments with maturities of 90 days or less when purchased. These investments consist of investments in money market funds with commercial banks and financial institutions. As of December 31, 2017, $114,500 of the Company's cash and cash equivalents were held in Russian banks, of which $111,600 was denominated in rubles with the remaining $2,900 denominated in U.S. dollars.

Short-Term Investments

The Company's short-term investments are classified as available for sale and held to maturity. Short-term investments consisted of United States Treasury securities in the amount of $3.6 million which were owned by CBLI and had maturities of less than 12 months. Accordingly, these investments are carried at fair market value. In addition, $1.0 million in certificates of deposit with maturity dates beyond three months and less than one year, and owned by Panacela, are also included. These investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. Unrealized gains and losses on available for-sale investments are reported as Other Comprehensive Loss, a separate component of stockholders' equity. Realized gains and losses, and interest and dividends on available-for-sale securities are recorded in our Consolidated Statement of Operations as Interest and Other Income (Expense). The cost of securities sold is based on the specific identification method.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains cash balances with financial institutions in excess of insured limits.

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As of December 31, 2017, the Company held 3% of its cash and cash equivalents in accounts located outside of the United States.

As of February 14, 2018, the Dollar:Russian Ruble exchange rate increased from 57.6002 to 57.7701, resulting in a decrease of $(0.3) thousand to the Company's cash and cash equivalents as compared to December 31, 2017.

Significant Customers and Accounts Receivable

The following table presents our revenue by customer, on a proportional basis, for the periods indicated:

	Years ended December 31,					
	2017		2016		Variance	
U.S. Department of Defense	69.0	%	35.4	%	33.6	%
Russian government agencies	—	%	46.9	%	(46.9	)%
Incuron, LLC	31.0	%	17.7	%	13.3	%
	100.0	%	100.0	%	—	%

Although the Company anticipates ongoing contract and grant revenue from these customers, there is no guarantee that these revenue streams will continue in the future.

The Company extends unsecured credit to its government customers under normal trade agreements and contracted terms, which generally require payment within 30 days. Accounts receivable consist of amounts due under contracts and grants from these customers, along with amounts receivable under subleases at our Buffalo, New York office facility. There were allowances for doubtful accounts of $0.2 million and $0.2 million at December 31, 2017 and December 31, 2016, respectively, pertaining to accounts receivable from our subleases.

Equipment

Equipment is stated at cost, net of accumulated depreciation. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repair and maintenance costs are expensed as incurred.

Equipment is depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

Asset Category	Estimated Useful Life (in Years)
Laboratory equipment	5
Furniture and fixtures	5
Computer equipment	3

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred, since the recoverability of such expenditures is uncertain. Upon marketability approval by the U.S. Food and Drug Administration ("FDA"), or a respective foreign regulatory governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

Deferred Revenue

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Deferred revenue represents cash received under grants and contracts in excess of the revenue recognizable through the end of the respective financial reporting period. The revenue associated with these advances will be recognized in future periods as the applicable costs are incurred.

Accrued Warrant Liability

Certain warrants are accounted for as derivative instruments in accordance with the Financial Accounting Standards Board Accounting Standards Codification (the "Codification") on derivatives and hedging as the warrant holders, under certain change of control situations, could require settlement in cash. As such, the warrants were initially recorded as liabilities based on their fair values on the date of issuance. Subsequent changes in the value of the warrants are recorded in the Statements of Operations as "Change in value of warrant liability."

The Company’s remaining outstanding warrants were treated as equity upon issuance and continue to be treated as equity since they did not contain any mandatory redemption features or other provisions that would require a different classification of these warrant instruments outside of permanent equity.

Foreign Currency Translation

The Russian ruble is the functional currency of our foreign subsidiaries, which are all located in the Russian Federation. Assets and liabilities of these companies are translated into U.S. dollars at the period-end exchange rate. Income and expense items are translated at the average exchange rates during the period. The net effect of this translation is recorded in the consolidated financial statements as accumulated other comprehensive income (loss).

Other Comprehensive Income/(Loss)

The Company applies the Codification on comprehensive income (loss) that requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The following table presents the changes in accumulated other comprehensive loss for the year ended December 31, 2017.

	Unrealized gain (loss) on available-for-sale securities	Gains and losses on foreign exchange translations	Total
Beginning balance	$ (2,286)	$(562,273)	$(564,559)
Other comprehensive income (loss) before reclassifications	362	47,740	48,102
Ending balance	$ (1,924)	$(514,533)	$(516,457)

Revenue Recognition

The Company generates grant and contract revenue from two different types of contractual arrangements: cost reimbursable grants and contracts, and fixed-price grants and contracts. Costs consist primarily of internal labor charges, subcontractors and materials, as well as an allocation of fringe benefits, overhead and general and administrative expenses, based on the terms of the contract. Under cost reimbursable grants and contracts, revenue is recognized during the period that the associated research and development costs are incurred. Under fixed-price grants and contracts, revenue is recognized using the percentage-of-completion method. The assumptions and estimates used in determination of the percentage-of-completion are developed in coordination with the principal investigator performing the work.

Research and Development

Research and development ("R&D") costs are expensed as incurred. R&D costs primarily consist of salaries, fringe benefits, and stock-based compensation for our clinical and scientific personnel along with a ratable share of our facility expenses. Other R&D expenses include fees paid to research-oriented consultants and outside service providers, and the costs of materials used in clinical trials and other research activities.

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Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended (the "Plan"), authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. At the 2015 annual meeting of stockholders, an amendment to increase the maximum number of shares of common stock reserved for issuance under the Plan was approved, and as of December 31, 2017, an aggregate of 650,000 shares of common stock were authorized for issuance under the Plan, of which a total of approximately 309,689 shares of common stock remained available for future awards. A single participant cannot be awarded more than 100,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by the CBLI board of directors.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. No options were granted during the years ended December 31, 2017 and 2016.

In June 2013, CBLI’s stockholders approved the 2013 Employee Stock Purchase Plan ("ESPP"), which provides a means by which eligible employees of CBLI, and certain designated related corporations, may be given an opportunity to purchase shares of CBLI common stock. As of December 31, 2017, there were 425,000 shares of common stock reserved for purchase under the ESPP. The number of shares reserved for purchase under the ESPP increases on January 1 of each calendar year by the lesser of (i) 10% of the total number of shares of common stock outstanding on December 31 of the preceding year, or (ii) 100,000 shares of common stock. The ESPP allows employees to use up to 15% of their compensation, up to $25,000 per year, to purchase shares of common stock at an amount equal to 85% of the fair market value of the our common stock on the offering date or the purchase date, whichever is less.

Income taxes

No income tax expense was recorded for the years ended December 31, 2017 and 2016, as the Company did not have taxable income for any of the years presented. A full valuation allowance has been recorded against the Company’s net deferred tax asset.

Earnings (loss) per share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

The Company has excluded the following outstanding warrants and options from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

	As of December 31,	
Common Equivalent Securities	2017	2016
Warrants	710,174	2,148,741
Options	211,487	233,367
Total	921,661	2,382,108

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash" ("ASU 2016-18"). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-

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of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-18 on its consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients" ("ASU 2016-12"). The amendments in ASU 2016-12 affect the guidance in ASU 2014-09 by clarifying certain specific aspects of the guidance, including assessment of collectability, treatment of sales taxes and contract modifications, and providing certain technical corrections. The pronouncement has the same effective date as ASU 2014-09, which is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. The Company is currently evaluating the impact of ASU 2016-12 on its consolidated financial statements. In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing" ("ASU 2016-10") related to identifying performance obligations and licensing. ASU 2016-10 is meant to clarify the guidance in FASB ASU 2014-09. Specifically, ASU 2016-10 addresses an entity’s identification of its performance obligations in a contract, as well as an entity’s evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. The pronouncement has the same effective date as ASU 2014-09. The Company is currently evaluating the impact of ASU 2016-10 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting" ("ASU 2016-09"). ASU 2016-09 affects entities that issue share-based payment awards to their employees. ASU 2016-09 is designed to simplify several aspects of accounting for share-based payment award transactions which include the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU 2016-09 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company adopted this pronouncement for the year ended December 31, 2016.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)" ("ASU 2016-02"). ASU 2016-02 will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated balance sheets and related disclosures.

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" ("ASU 2016-01"). The pronouncement requires equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset, and eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost. These changes become effective for the Company’s fiscal year beginning January 1, 2018. The expected adoption method of ASU 2016-01 is being evaluated by the Company and the adoption is not expected to have a significant impact on the Company’s consolidated financial position or results of operations.

In May 2014, the FASB issued Accounting Standards Update ("ASU 2014-9"), "Revenue from Contracts with Customers," which updates the principles for recognizing revenue. ASU 2014-9 also amends the required disclosures of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-9 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date" ("ASU 2015-14") which defers the effective date of ASU 2014-09 by one year. ASU 2014-9 is now effective for annual reporting periods after December 15, 2017

including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is evaluating the potential impacts of the new standard on its existing revenue recognition policies and procedures.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern" ("ASU 2014-15"), which requires that an entity’s management evaluate whether there are conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company adopted this pronouncement during the year ended December 31, 2016.

3. Fair Value Measurements

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The Company measures and records cash equivalents and warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

- Level 1 – Observable inputs for identical assets or liabilities such as quoted prices in active markets;
- Level 2 – Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 – Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2017 and 2016:

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$551,088	$—	$—	$551,088
Short-term investments	3,606,499	954,858	—	4,561,357
Total assets	$4,157,587	$954,858	$—	$5,112,445
Liabilities:				
Accrued warrant liability	$—	$—	$1,041,455	$1,041,455

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$2,436,589	$—	$—	$2,436,589
Short-term investments	7,487,365	856,292	—	8,343,657
Total assets	$9,923,954	$856,292	$—	$10,780,246
Liabilities:				
Accrued warrant liability	$—	$—	$949,419	$949,419
Total liabilities	$—	$—	$949,419	$949,419

The Company has certain warrants that could require settlement in cash if a fundamental transaction occurs, as defined in the respective agreements. These agreements specify the amount due to warrant holders is based on the Black-Scholes pricing model.

The following are the assumptions used to measure the accrued warrant liability at December 31, 2017 and 2016:

"Risk-free interest rate" means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

"Expected dividend yield" means the anticipated dividend return for an investor over the expected life. For the Company, this amount is zero as it is not anticipated that dividends will be paid for the foreseeable future.

"Expected life" means the period of time that options granted are expected to remain outstanding, based wholly on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not yet have adequate historical exercise information to estimate the expected life the options granted.

"Expected volatility" means a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Expected volatility is based on the Company's historical volatility and incorporates the volatility of the common stock of comparable companies when the

expected life of the option exceeds the Company's trading history.

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	December 31,	
	2017	2016
Stock Price	$4.01	$ 1.42
Exercise Price	$ 3.00 - 24.40	$ 3.00 - 60.00
Term in years	0.25 - 3.60	0.17 - 4.60
Volatility	71.48 - 132.88%	92.58% 96.36%
Annual rate of quarterly dividends	0 %	0 %
Discount rate- bond equivalent yield	0.44 - 2.05%	.15 - 1.84%

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurement of the accrued warrant liability for the years ended December 31, 2017 and 2016:

	Year Ended December 31, 2017
Beginning Balance	$ 949,419
Total (gains) or losses, realized and unrealized, included in earnings (1)	4,426,146
Settlements	(4,334,110)
Balance at, December 31, 2017	$ 1,041,455

	Year Ended December 31, 2016
Beginning Balance	$ 4,048,900
Total (gains) or losses, realized and unrealized, included in earnings (1)	(3,099,481)
Balance at, December 31, 2016	$ 949,419

(1) Unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of December 31, 2017 and 2016, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability measurement to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. The following table summarizes the unobservable inputs into the fair value measurements:

	December 31, 2017			
Description	Fair Value	Valuation Technique	Unobservable Input	Range in years
Accrued warrant liability	$ 1,041,455	Black-scholes pricing model	Expected term	0.25 - 3.60

Management believes the value of the accrued warrant liability is more sensitive to changes in the Company's stock price at the end of the respective reporting period as opposed to changes in the expected term. At December 31, 2017, a 10% increase in the expected term of the Company's warrants measured using the Black-Scholes pricing model would increase the warrant liability by approximately 2%, while a 10% decrease in the expected term would decrease the warrant liability by approximately 2%. A 10% increase in the Company's stock price would result in an increase in the accrued warrant liability of approximately 16%, while a 10% decrease in the stock price would decrease the

warrant liability by approximately 16%.

The carrying amounts of the Company’s remaining financial instruments, which include cash, short-term investments, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

4. Equipment

The following table summarizes the value of the Company’s equipment as of December 31, 2017 and 2016:

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	As of December 31,	
	2017	2016
Computer equipment	$208,943	$205,280
Lab equipment	554,880	575,793
Furniture	500,202	500,202
	1,264,025	1,281,275
Less accumulated depreciation	(1,245,437)	(1,243,899)
Equipment, net	$18,588	$37,376

5. Equity Awards

Warrants

In connection with sales of the Company's common stock and the issuance of debt instruments that have since been repaid, warrants were issued. The warrants expire between one and seven years from issuance from the date of grant, and are subject to the terms applicable in each agreement. The following table sets forth the changes in the number of warrants outstanding for the periods presented:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2015	2,222,155	$ 13.98
Forfeited, Canceled	(73,414)	100.00
Outstanding at December 31, 2016	2,148,741	11.04
Exercised	(1,181,235)	3.64
Forfeited, Canceled	(257,332)	50.76
Outstanding at December 31, 2017	710,174	8.95

During April 2017, warrant holders exercised 1,181,235 warrants for 292,668 shares of the Company's common stock through cashless exercise. The fair value of the warrants exercised was valued using the Black Scholes option pricing model based on the following assumptions:

Stock Price	$ 4.84
Exercise Price	$ 3.64
Term in years	4.29
Volatility	101.93%
Annual rate of quarterly dividends	0 %
Discount rate- bond equivalent yield	1.65 %

Equity Incentive Plan

The following is a summary of option award activity under the Plan for the year ended December 31, 2017:

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	Year Ended December 31, 2017			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2016	233,367	$ 41.98	—	$ —
Granted	—	—	—	—
Vested	—	—	—	—
Exercised	—	—	—	—
Forfeited, Canceled	(21,880)	90.70	—	—
December 31, 2017	211,487	36.94	—	—

The following is a summary of outstanding stock options under the Plan as of December 31, 2017:

	Stock Options Outstanding	Vested Stock Options
Quantity	211,487	211,487
Weighted-average exercise price	$ 36.94	$ 36.94
Weighted Average Remaining Contractual Term (in Years)	5.26	5.26
Intrinsic value	$ 65,382	$ —

For the years ended December 31, 2017 and 2016, the Company granted no stock options. For the years ended December 31, 2017 and 2016, the total fair value of options vested was $0, and $83,789, respectively. The total intrinsic value of options exercised for the years ended December 31, 2017 and 2016 was $0, and $0, respectively. As of December 31, 2017, there was no total compensation cost not yet recognized related to unvested stock options.

6. Significant Alliances and Related Parties

Roswell Park Cancer Institute

The Company has entered into several agreements with Roswell Park Cancer Institute ("RPCI"), including: various sponsored research agreements, an exclusive license agreement and clinical trial agreements for the conduct of the Phase 1 entolimod oncology study and the Phase 1 CBL0137 intravenous administration study. Additionally, the Company’s Chief Scientific Officer, Dr. Andrei Gudkov, is the Senior Vice President of Basic Research at RPCI. The Company incurred $55,299 and $635,187 in expense to RPCI related to research grants and agreements for the years ended December 31, 2017 and 2016, respectively. The Company had $8,391 and $91,928 included in accounts payable owed to RPCI at December 31, 2017 and 2016, respectively. In addition, the Company had $84,429 and $110,487 in accrued expenses payable to RPCI at December 31, 2017 and 2016, respectively.

The Cleveland Clinic

CBLI entered into an exclusive license agreement, or the License, with The Cleveland Clinic ("CCF"), pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic’s research base underlying our therapeutic platform and certain product candidates in development by Panacela. CBLI has the primary responsibility to fund all newly developed patents; however, CCF retains ownership of those patents covered by the agreement. CBLI also agreed to use commercially diligent efforts to bring one or more products to market as soon as practical, consistent with sound and reasonable business practices and judgments. In consideration for the License, CBLI agreed to issue CCF common stock and make certain milestone, royalty and sublicense royalty payments. Milestone payments, which may be credited against future royalties, amounted to $0, and $0 for the years ended December 31, 2017 and 2016, respectively. No royalty or sublicense royalty payments were made to CCF during the two-year period ended December 31, 2017.

The Company also recognized $11,700, and $0 as research and development expense to CCF for the years ended December 31, 2017 and 2016, respectively. The Company had $11,700 and $0 included in accrued expenses payable at December 31, 2017 and 2016, respectively.

Buffalo BioLabs and Incuron

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Our Chief Scientific Officer, Dr. Andrei Gudkov has business relationships with several entities with which we transact business, the most significant of which is Buffalo BioLabs ("BBL"), where Dr. Gudkov was a founder and currently serves as its Principal Scientific Adviser. Pursuant to a master services agreement we have with BBL, the Company recognized $197,900 and $730,164 as research and development expense payable to BBL for the years ended December 31, 2017 and 2016, respectively, and included $0 and $1,319 in accounts payable to BBL at December 31, 2017 and 2016, respectively. In addition, the Company had $13,889 and $23,500 in accrued expenses payable to BBL at December 31, 2017 and 2016, respectively. We also recognized $42,361 and $90,607 from BBL for sublease and other income for the years ended December 31, 2017 and 2016, respectively. Pursuant to our real estate sublease and equipment lease with BBL, we had gross and net accounts receivable of $202,151 and $0 from BBL at December 31, 2017 and gross and net accounts receivables of $209,853 and $7,702 from BBL at December 31, 2016, respectively.

Dr. Gudkov is also an uncompensated member of the board of directors for Incuron. Pursuant to master service and development agreements we have with Incuron, the Company performs various research, business development, clinical advisory, and management services. We recognized revenue of $604,010 and $622,360 from Incuron for the years ended December 31, 2017 and 2016, respectively. In addition, we also recognized $7,104 and $7,104 from Incuron for sublease and other income for the years ended December 31, 2017 and 2016, respectively. Pursuant to these agreements, we had gross accounts receivable of $158,651 and $70,659 at December 31, 2017 and 2016, respectively.

Exacte Labs, LLC

Our majority owned subsidiary's Chief Executive Officer also serves as the Chief Executive Officer of Exacte Labs, LLC a Contract Research Organization ("CRO") with which BioLab 612 transacted business during 2017. BioLab 612 incurred $14,447 in expense to Exacte Labs for the year ended December 31, 2017.

7. Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred taxes are determined by calculating the future tax consequences attributable to differences between the financial accounting and tax bases of existing assets and liabilities. A valuation allowance is recorded against deferred tax assets when, in the opinion of management, it is more likely than not that the Company will not be able to realize the benefit from its deferred tax assets.

The Company files income tax returns, as prescribed by the national, state and local jurisdictions in which it operates. The Company’s uncertain tax positions are related to tax years that remain subject to examination and are recognized in the financial statements when the recognition threshold and measurement attributes are met. Interest and penalties related to tax deficiencies and uncertain tax positions are recorded as income tax expense.

Income (Loss) from continuing operations consists of the following:

	For the Year Ended December 31,	
	2017	2016
US operations	$(9,315,082)	$(2,010,415)
Foreign operations	(527,590)	(579,644)
	$(9,842,672)	$(2,590,059)

The provision for income taxes charged to continuing operations is $0 for all periods presented.

Deferred tax assets (liabilities) were comprised of the following as of the periods presented below:

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	As of December 31,	
	2017	2016
Deferred tax assets:		
Operating loss carryforwards	$34,427,000	$50,687,000
Accrued expenses	5,969,000	8,781,000
Tax credit carryforwards	3,864,000	3,747,000
Intellectual property	3,878,000	4,097,000
Equipment	150,000	283,000
Total deferred tax assets	48,288,000	67,595,000
Deferred tax liabilities:	—	—
Net deferred tax asset	48,288,000	67,595,000
Valuation allowance	(48,288,000)	(67,595,000)
	$—	$—

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to the pretax loss from continuing operations as a result of the following differences:

	For the Year Ended December 31,	
	2017	2016
Tax at the U.S. statutory rate	$(3,347,000)	$(881,000)
Change in value of warrant liability	1,505,000	(1,054,000)
Valuation allowance	1,841,000	1,933,000
Other	1,000	2,000
	$—	$—

At December 31, 2017, the Company had U.S. federal net operating loss carryforwards of approximately $139.7 million, which begin to expire if not utilized by 2023, and approximately $4,046,000 of tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has state net operating loss carryforwards of approximately $84.2 million, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $311,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich on July 9, 2015 resulted in Mr. Davidovich owning 60.2% of the Company, at that time. We therefore believe it highly likely that this transaction will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code. Consequently, our ability to utilize approximately $124.8 million of U.S. federal net operating loss carryforwards, $3.65 million of U.S. tax credit carryforwards, approximately $73.4 million of state net operating loss carryforwards, and $324,000 of state tax credit carryforwards, all of which occurred prior to July 9, 2015, are limited. As such, a significant portion of these carryforwards will likely expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carryforwards.

The Company files U.S. federal income tax returns, along with various state and foreign income tax returns. All federal, state and foreign tax returns for the years ended December 31, 2016, 2015 and 2014 are still open for examination.

The following presents a roll-forward of the unrecognized tax benefits and the associated interest and penalties:

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	Unrecognized Tax Benefits	Interest and Penalties
Balance at January 1, 2016	$ 468,000	$ —
Prior year tax position	—	—
Current year tax position	—	—
Deferred tax position	14,000	—
Settlements with tax authorities	—	—
Expiration of the statute of limitations	—	—
Balance at December 31, 2016	482,000	—
Prior year tax position	—	—
Current year tax position	—	—
Deferred tax position	11,000	—
Settlements with tax authorities	—	—
Expiration of the statute of limitations	—	—
Balance at December 31, 2017	$ 493,000	$ —

CBLI claimed New York State incentive tax credit refunds of $48,000 and $60,000 during 2017 and 2016, respectively. These refundable tax credits were based on the Company’s research and development activities, real estate tax payments, employment levels and equipment purchases. Since there is no state tax liability or refund of prior year tax payments, these refundable tax credits were recorded against operating expenses in the year of receipt, instead of being recorded as an income tax benefit.

The U.S. government enacted the Tax Cuts and Jobs Act (the "Tax Act") on December 22, 2017, which made several changes to U.S. tax laws that could have a significant impact on the Company. Most of these provisions are effective for tax years beginning after December 31, 2017, and include, but are not limited to, (1) a reduction in the corporate tax rate from 34% to 21%, (2) limitations on the utilization of operating loss carryforwards, (3) limitations on the utilization of interest deductions, (4) requiring a one-time transition tax on undistributed earnings of foreign subsidiaries, (5) elimination of U.S. taxes on dividends received from foreign subsidiaries, (6) implementing a base erosion tax, and (7) implementing a new provision designed to tax currently in the U.S. global intangible low-taxed income ("GILTI") of foreign subsidiaries.

U.S. GAAP requires the impact of tax legislation to be recorded in the period of enactment. Accordingly, the Company's deferred tax assets were reduced by approximately $21.5 million to reflect the lower tax rate that will apply going forward, however, there was no income tax expense given the existence of a full valuation allowance recorded against the deferred tax assets.

None of the Company's foreign subsidiaries have undistributed earnings, so there is no impact associated with the one-time transition tax. Going forward, a tax liability could exist under the new GILTI provisions, but that will not apply until the foreign subsidiaries begin to generate income. The timing and amount of income to be generated by the foreign subsidiaries, and the impact of the new GILTI provision is impossible to estimate at this time, and therefore, no impact has been recorded.

8. Employee Benefit Plan

CBLI maintains an active defined contribution retirement plan for its employees, referred to herein as the Benefit Plan. All employees satisfying certain service requirements are eligible to participate in the Benefit Plan. The Company makes matching cash contributions each payroll period, up to 4% of employees’ salaries. The Company’s expense relating to the Benefit Plan was $40,962, and $48,334 for the years ended December 31, 2017, and 2016, respectively.

9. Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include fixed obligations to sponsor research and development activities, make

minimum royalty payments for licensed patents and pay additional amounts that may be required upon the achievement of scientific, regulatory and commercial milestones, including milestones such as the submission of an IND to the FDA and the first commercial sale of the Company's products in various countries. As of December 31, 2017 the Company is uncertain as to whether any of these contingent events

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will become realized. There were no milestone payments or royalties on net sales accrued for any of these agreements as of December 31, 2017 and 2016.

From time-to-time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings.

The Company has entered into agreements with substantially all of our employees who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

As of December 31, 2017, the Company had unconditional purchase obligations totaling $405,920 for goods and services, substantially all of which the Company anticipates to incur during 2018.

Capital Lease

In December 2011, the Company entered into a capital lease for scientific equipment. The terms of the lease required an upfront payment and monthly payments once the lease term began in March 2012. Principal and interest payments under the capital lease obligation were $0, and $0 during the years ended December 31, 2017 and 2016, respectively. As of March 31, 2016, the equipment purchased pursuant to the capital lease was sold, which resulted in a one-time gain of $115,049 that was reported as Other Income in the Company's Consolidated Statement of Operations for the year ended December 31, 2016. At the time of the sale, the accumulated depreciation for the equipment was $62,111.

Operating Leases

The Company leases laboratory facilities and office facilities at various locations with expiration dates ranging from 2018 to 2019. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. For the years ended December 31, 2017 and 2016, total rent expense related to the Company’s operating leases was $401,455 and $388,355, respectively. In addition, the Company has subleased some of its facilities.

As of December 31, 2017, future minimum payments under operating leases are as follows:

2018	$386,429
2019	191,048
2020	—
Total minimum lease payments	$577,477

Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A: Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), as of December 31, 2017. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2017, our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal financial officer) concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (2) accumulated and communicated to our management, including our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal financial officer), as appropriate to allow timely decisions regarding required disclosure.

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Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of management, including our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal financial officer), we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2017.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our fourth fiscal quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B: Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for the 2018 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Executive Officer and Director Compensation" in our Proxy Statement for the 2018 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement for the 2018 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Person Transactions" and "Management and Corporate Governance" in our Proxy Statement for the 2018 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Registered Public Accounting Firm" in our Proxy Statement for the 2018 Annual Meeting of Stockholders.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this report:

(1) Financial Statements, included in Part II, Item 8. "Financial Statements and Supplementary Data":

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2017 and 2016

Consolidated Statements of Operations for the years ended December 31, 2017 and 2016

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016

Consolidated Statement of Stockholders' Equity as of December 31, 2017 and 2016

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

None.

(3) Index to Exhibits: The exhibits listed in the following Exhibit Index are filed with this report or, as noted, incorporated by reference herein.

Exhibit No.	Identification of Exhibit
3.1	Restated Certificate of Incorporation filed with the Secretary of State of Delaware on March 18, 2010 (Incorporated by reference to Exhibit 3.1 to Form 10-K for the year ended December 31, 2009, filed on March 22, 2010).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013 (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended June 30, 2013, filed on August 9, 2013).
3.3	Certificate of Amendment of Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 27, 2015).
3.4	Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 20, 2016 (incorporated by reference to Exhibit 3.4 to Form 10-Q for the period ended March 31, 2016, filed May 16, 2016.
3.5	Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 21, 2017 (incorporated by reference to Exhibit 3.5 to Form 10-Q for the period ended March 31, 2017, filed May 15, 2017.
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 9, 2015).
3.7	Certificate of Amendment of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed on February 9, 2015).
3.8	Second Amended and Restated By-Laws (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 5, 2007).
3.9	Amendment to Second Amended and Restated By-Laws of Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 18, 2015).
4.0	Form of Common Stock Purchase Warrant (Series D Transaction) (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on March 30, 2009).
4.1	Form of Series F Warrants (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 21, 2011).
4.2	Warrant Agreement, dated September 30, 2013, between Cleveland BioLabs, Inc. and Hercules Technology II, L.P. (Incorporated by reference to Exhibit 4.2 to Form 10-Q for the period ended September 30, 2013, filed on November 8, 2013).

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Exhibit No.	Identification of Exhibit
4.3.1	Form of Series A Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 15, 2014).
4.3.2	Amendment to Series A Common Stock Purchase Warrant, dated September 4, 2014, by and between Cleveland BioLabs, Inc.,Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (Incorporated by reference to Exhibit 4.1 and Exhibit 4.2 to Form 8-K filed on September 8, 2014).
4.4	Form of Series J Warrant Agreement (Incorporated by reference to Exhibit 4.1 Form 8-K filed on June 20, 2014).
4.5	Form of Series A Warrant to Purchase Common Stock, as amended to date (Incorporated by reference to Exhibit 4.2 to Form 8-K filed on February 9, 2015).
10.0	Amendment No. 1 to Securities Purchase Agreement and Series D Warrants, dated September 29, 2014, by and among Cleveland BioLabs, Inc. and the parties on the signature pages thereto (Incorporated by reference to Exhibit 10.1 Form 8-K filed on October 2, 2014).
10.1	Amendment No. 1 to Securities Purchase Agreement, dated February 25, 2010, by and among Cleveland BioLabs, Inc., and the Purchasers set forth therein (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 13, 2015).
10.2	Registration Rights Agreement, dated June 17, 2014, by and among Cleveland BioLabs, Inc., and the purchasers on Exhibit A thereto (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 20, 2014).
10.3	Securities Purchase Agreement, dated February 4, 2015, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein, as amended to date (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 9, 2015).
10.4	Registration Rights Agreement, dated February 4, 2015, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 9, 2015).
10.5	Securities Purchase Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 24, 2015).
10.6	Registration Rights Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 24, 2015).
10.7	Stock Subscription Agreement, dated as of December 18, 2015, between Cleveland BioLabs, Inc. and Open Joint Stock Company "Rusnano" (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 24, 2015).
10.8	Stock Subscription Agreement, dated as of December 18, 2015, between Panacela Labs, Inc. and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on December 24, 2015).
10.9	Stock Subscription Agreement, dated as of December 18, 2015, between Panacela Labs, Inc. and Open Joint Stock Company "Rusnano" (Incorporated by reference to Exhibit 10.3 to Form 8-K filed on December 24, 2015).
10.10	Acknowledgement Agreement, dated as of December 18, 2015, among Cleveland BioLabs, Inc., Panacela Labs, Inc. and Open Joint Stock Company "Rusnano" (Incorporated by reference to Exhibit 10.4 to Form 8-K filed on December 24, 2015).
10.11	Exclusive License Agreement by and between The Cleveland Clinic Foundation and Cleveland BioLabs, Inc., effective as of July 1, 2004 (Incorporated by reference to Exhibit 10.8 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.12†	Second Amendment to Exclusive License Agreement, dated September 22, 2011, by and between The Cleveland Clinic Foundation and the registrant (Incorporated by reference to Exhibit 10.3 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.13	

	Library Access Agreement by and between ChemBridge Corporation and Cleveland BioLabs, Inc., effective as of April 27, 2004 (Incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.14	Restricted Stock and Investor Rights Agreement between Cleveland BioLabs, Inc. and ChemBridge Corporation, dated as of April 27, 2004 (Incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.15	Process Development and Manufacturing Agreement between Cleveland BioLabs, Inc. and SynCo Bio Partners B.V., effective as of August 31, 2006 (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 25, 2006).
10.16	Sponsored Research Agreement between Cleveland BioLabs, Inc. and Roswell Park Cancer Institute Corporation, effective as of January 12, 2007 (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 12, 2007).
10.17	Investment Agreement, dated September 19, 2011, by and among Panacela Labs, Inc., the Registrant and Open Joint Stock Company Rusnano (Incorporated by reference to Exhibit 10.1 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).

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Exhibit No.	Identification of Exhibit
10.18†	Exclusive License and Option Agreement, dated September 23, 2011, by and between Children's Cancer Institute Australia for Medical Research and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.2 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.19†	Exclusive License and Option Agreement, dated September 23, 2011, by and between Health Research, Inc., Roswell Park Institute Division, Roswell Park Cancer Institute Corporation, and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.4 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.20	Amended and Restated Exclusive Sublicense Agreement, dated September 23, 2011, by and between the registrant and Panacela Labs, Inc. (Incorporated by reference to Exhibit 10.5 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.21	Assignment Agreement, dated September 23, 2011, by and between Panacela Labs, Inc. and the registrant (Incorporated by reference to Exhibit 10.7 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.22	Master Services Agreement, dated October 14, 2013, between Buffalo BioLabs, LLC and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 18, 2013).
10.23	Cooperative Research and Development Agreement by and between the Uniformed Services University of the Health Sciences, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., the Cleveland Clinic Foundation, and Cleveland BioLabs, Inc., dated as of August 1, 2004 (Incorporated by reference to Exhibit 10.9 to Form 10-Q for the period ended September 30, 2010, filed on November 15, 2010).
10.24†	Award/Contract W81XWH-15-C-0101 dated September 1, 2015 issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.4 to Form 10-Q filed on November 9, 2015).
10.25†	Award/Contract W81XWH-15-1-0570 dated September 30, 2015 by issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.5 to Form 10-Q filed on November 9, 2015).
10.26†	Award/Contract W81XWH-15-C-0101 modification dated October 4, 2016 issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.1 to Form 10-Q filed November 14, 2016.
10.27†	Award/Contract W81XWH-15-C-0101 modification dated September 14, 2017 issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.1 to Form 10-Q filed November 14, 2017.
10.28	Master Purchase Agreement dated April 29, 2015 by and among Cleveland BioLabs, Inc., Mikhail Mogutov and Incuron LLC (Incorporated by reference to Exhibit 2.1 to Form 8-K filed on May 4, 2015).
10.29	Option Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Mikhail Mogutov (Incorporated by reference to Exhibit 2.2 to Form 8-K filed on May 4, 2015).
10.30	Royalty Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Incuron LLC (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 4, 2015).
10.31	Master Services Agreement, dated June 1, 2010, between Incuron, LLC and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.3 to Form 10-K filed on February 22, 2017).
10.32	Master Development Agreement, dated July 1, 2010, between Incuron, LLC and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.31 to Form 10-K filed on February 22, 2017).
10.33*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Langdon Miller (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on July 10, 2015).
10.34*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Andrei Gudkov (Incorporated by reference to Exhibit 10.3 to Form 8-K filed on July 10, 2015).
10.35*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Yakov Kogan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 10, 2015).
10.36*	Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Appendix A to Proxy Statement on Schedule 14A filed on April 1, 2008).

10.37*	First Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 9, 2010).
10.38*	Second Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 15, 2012).
10.39*	Third Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 17, 2015).
10.40*	Form of Stock Award Grant Agreement (Incorporated by reference to Exhibit 99.2 to Form 8-K filed on June 15, 2012).
10.41*	Form of Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 99.3 to Form 8-K filed on June 15, 2012).

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Exhibit No.	Identification of Exhibit
10.42*	Cleveland BioLabs, Inc. 2013 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 20, 2013).
10.43*	First Amendment to Cleveland BioLabs, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on April 17, 2015).
10.44*	2012 Long-term Executive Compensation Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 15, 2012).
10.45*	Severance Benefit Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 13, 2014).
21.1	Subsidiaries
23.1	Consent of Meaden & Moore, Ltd.
31.1	Rule 13a-14(a)/15d-14(a) Certification of Yakov Kogan
32.1	Section 1350 Certification.
101.1	The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K for the quarter and year ended December 31, 2017: (i) Consolidated Balance Sheets at December 31, 2017 and 2016; (ii) Consolidated Statements of Operations for years ended December 31, 2017 and 2016; (iii) Consolidated Statements of Comprehensive Income (Loss) for years ended December 31, 2017 and 2016; (iv) Consolidated Statements of Stockholders' Equity for years ended December 31, 2017 and 2016; (v) Consolidated Statements of Cash Flows for years ended December 31, 2017 and 2016; and (vi) Notes to Consolidated Financial Statements as blocks of text.

† Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

* Indicates management contract or compensatory plan required to be filed as an Exhibit.

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Item 16. Form 10-K Summary
Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: 3/6/2018 By: /s/ YAKOV KOGAN
Yakov Kogan
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/S/ Yakov Kogan Yakov Kogan	Chief Executive Officer and Director (principal executive officer and principal financial officer)	March 6, 2018
/S/ Lea Verny Lea Verny	Director	March 6, 2018
/S/ Randy Saluck Randy Saluck	Director	March 6, 2018
/S/ Alexander Andryushechkin Alexander Andryushechkin	Director	March 6, 2018
/S/ Anna Evdokimova Anna Evdokimova	Director	March 6, 2018
/S/ Ivan Persiyanov Ivan Persiyanov	Director	March 6, 2018
/S/ Alexey Nechaev Alexey Nechaev	Director	March 6, 2018

/S/ Daniil Talyanskiy Daniil Talyanskiy	Director	March 6, 2018